EXHIBITS 51-54 REDACTED IN THEIR ENTIRETY

EXHIBIT 55

The Influence of Antisense Oligonucleotide Length on Dystrophin Exon Skipping

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Antisense oligonucleotides (AOs) can be used to redirect dystrophin pre-messenger RNA (mRNA) processing, to remove selected exons from the mature dystrophin mRNA, to overcome nonsense mutations, and/or restore the reading frame. Redundancy within the dystrophin protein allows some domains to be removed without seriously compromising function. One of the challenges for splicing blockade is to design AOs that efficiently remove targeted exons across the dystrophin pre-mRNA. AOs are initially designed to anneal to the more obvious motifs implicated in the splicing process, such as acceptor or donor splice sites and *in silico* predicted exonic splicing enhancers. The AOs are evaluated for their ability to induce targeted exon skipping after transfection into cultured myoblasts. Although no single motif has been implicated in the consistent induction of exon skipping, the length of the AO has emerged as an important parameter in designing compounds that redirect dystrophin pre-mRNA processing. We present data from *in vitro* studies in murine and human cells showing that appropriately designed AOs of 25–31 nucleotides are generally more effective at inducing exon skipping than shorter counterparts. However, there appears to be an upper limit in optimal length, which may have to be established on a case-by-case basis.

Received 26 March 2006; accepted 24 August 2006.
doi:10.1038/sj.mt.6300006

INTRODUCTION

Duchenne muscular dystrophy (DMD) is a severe and debilitating disorder arising from mutations within the dystrophin gene that preclude synthesis of functional dystrophin protein.[1] Dystrophin is a crucial structural protein that anchors cytoskeletal actin to the sarcolemmal membrane in skeletal and smooth muscle cells.[2] In the absence of functional dystrophin, normal muscle contractions cause injury to the sarcolemmal membrane. In response to repeated membrane damage, the regenerative capacity of the muscle is overwhelmed, and the tissue is replaced by adipose and fibrous material (for a review see refs. 3,4).

The human dystrophin gene is the largest known and has 79 exons spanning 2.4 million bases.[5] The most common type of dystrophin mutation is a genomic deletion of one or more exons, occurring predominately in two hotspots involving the 5′ end and exons 44–55.[6] However, approximately one-third of mutations are more subtle DNA changes (nonsense mutations, splicing defects, micro-deletions/insertions) and these appear to be spread across the entire dystrophin gene (for a review see ref. 4).

Becker muscular dystrophy also arises from dystrophin gene defects, but these are typically in-frame deletions that still allow production of shorter but partially functional dystrophin protein.[7] Depending upon the position and size of these in-frame deletions, clinical progression can be delayed and associated with mild to barely detectable symptoms.[8] For example, one Becker muscular dystrophy patient had such mild symptoms that he was not diagnosed with an exon 3–9 deletion until the age of 65 years.[9] Another patient with a 12 exon deletion (exons 33–44) only experienced mild muscular cramping after intensive exercise.[10]

Antisense oligonucleotides (AOs) have been used to mask abnormal or cryptic splice sites and restore normal pre-messenger RNA (mRNA) processing.[11] AOs may be applied to a dystrophin gene transcript, carrying a protein-truncating mutation, to target normal splice motifs and induce abnormal splicing to remove the exon carrying the nonsense mutation or restore the reading frame around a deletion.[12] Many aspects of the dystrophin gene, such as size, and the complexity of processing and expression, which have proved to be great challenges for gene repair or replacement,[13] may be regarded as positive features with respect to AO-induced exon skipping.

The *mdx* mouse model of muscular dystrophy[14] arises from a nonsense mutation in dystrophin exon 23 that precludes the synthesis of a full-length dystrophin protein.[15] Although this animal model does not reflect the clinical severity of DMD, the *mdx* mouse has been useful in studying dystrophin at the molecular level. Initial attempts to overcome this *mdx* mutation by AO-induced exon skipping used a 12mer of 2′-*O*-methyl bases on a phosphorothioate backbone targeting the acceptor site of

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intron 22, but precise removal of exon 23 was not demonstrated *in vitro*.[16] Wilton *et al.*[12] designed a 20mer, designated M23D(+12−08), directed at the *mdx* mouse exon 23 donor splice site, which induced consistent exon 23 skipping in a dose-dependent manner. The first refinement to AO design was made with M23D(+12−13), which targeted the same coordinates with additional intronic sequence.[17] A subsequent improvement was then achieved with a 20mer that annealed to the last two bases of exon 23 and the first 18 bases of intron 23, M23D(+02−18).[17] Here, we report further enhancement of exon skipping with M23D(+07−18) directed at the same donor splice site, and show that AO length can play a crucial role in determining efficiency of targeted exon removal. We have found this trend extends to other splice sites in the human dystrophin gene transcript and report enhanced exon skipping of human dystrophin exons 16, 51, and 53 with optimized AOs.

RESULTS

For a full explanation of AO nomenclature, please refer to the **Table 1** legend.

Murine studies

Four AOs, a 20mer M23D(+02−18), the 25mer M23D(+07−18), and two 30mers M23D(+12−18) and M23D(+07−23) (**Table 1**), were compared for their ability to induce exon 23 skipping in the *mdx* dystrophin mRNA. As shown in **Figure 1**, both the 20 and 25mers induced exon skipping at 10 nM concentration; however, the 25mer was consistently able to induce more pronounced exon skipping at day 1 (**Figure 1a** and **b**). After transfection at 100 and 200 nM, the 25mer induced approximately 74 and 82% exon skipping, respectively, whereas the 20mer induced 32 and 68% exon skipping at equivalent concentrations, based upon densitometry using a Chemi-Smart 3,000 gel documentation system and Bio-1D analysis software (Vilber Lourmat, Marne La Vallee).

The 20 and 25mers were then compared for their ability to induce sustained exon skipping at 3, 5, and 7 days after transfection. Three days after transfection, the 20mer only induced weak exon skipping at 25 nM whereas M23D(+07−18) was still able to induce exon skipping at 10 nM concentration (**Figure 1c** and **d**). Although exon skipping in cells treated with the 20mer was barely detectable at day 5, the 25mer induced moderate levels of exon skipping at 200 nM with some exon skipping still observed 5 days after transfection at 50 nM (**Figure 1e** and **f**). No detectable exon skipping was induced by the 20mer, and only low levels of exon skipping were observed after transfection with the 25mer at 100 nM at day 7 (data not shown).

In contrast to the high levels of exon skipping induced by the 20mer and 25mer, the two 30mers had little effect on exon 23 exclusion from the mature dystrophin mRNA. The two 30mers, which span the same site as the most effective AO, M23D(+07−18), but extend annealing by five nucleotides in the 5′ or 3′ directions, were unable to induce efficient exon 23 exclusion (**Figure 1g** and **h**). Note that M23D(+07−23) appeared marginally more effective at exon 23 excision than the other 30mer M23D(+12−18).

Human studies

A panel of AOs was directed at acceptor, donor, and exonic splicing enhance (ESE) sites within human dystrophin exon 16 (**Table 1**). Serine-arginine (SR)-rich proteins are involved in exon selection during splicing and predicted SR protein binding sites for exon 16 are shown in **Figure 2a**. The locations of AOs directed at and near the acceptor site are shown in the expanded detail. AOs targeting the donor site were ineffective (data not shown), whereas masking an intra-exonic domain predicted to contain ESEs with H16A(+87+109) induced only moderate exon 16 skipping (data not shown). However, annealing a 25mer, H16A(−06+19) targeted to the acceptor site and adjacent putative ESEs, induced enhanced exon 16 removal (**Figure 2b**) compared to that induced by H16A(+87+109). A series of AOs were subsequently designed to this region to further refine and optimize induced exon skipping. The majority of AOs directed at or near the exon 16 acceptor site were found to induce consistent exon skipping, generally in a dose-dependent manner; however, there was considerable variation in efficiency of exon 16 removal (**Figure 2b–g**). The two 31mers induced strong exon skipping at 10 nM (**Figure 2e** and **f**) and the only AO that failed to induce exon 16 skipping was a 20mer, H16A(−07+13) (**Figure 2g**), despite this compound annealing to sequences common to both the 31mers that efficiently dislodged exon 16 from the mature mRNA.

Table 2 summarizes the exon skipping potential of each AO observed after *in vitro* transfection, and also indicates weighted matrix values of predicted SR motifs that are masked by AOs designed to the target exons. It should be noted that an AO may mask more than one SR motif.

Exon 51 skipping could be induced at low levels by several AOs directed at various intra-exonic targets (**Table 2**). However, enhanced exon skipping was identified after targeting one region with H51A(+66+90) and H51A(+66+95), but in this particular example, there was only a minor improvement in induced exon skipping when using the longer AO (**Figure 3**). Data from two separate experiments are shown in **Figure 3a** and **b** to demonstrate reproducibility of exon skipping *in vitro*.

AO-induced exon 53 removal also showed similar trends to exon 51 in that many of the AOs induced low levels of exon skipping, but only when applied at high concentrations of 200 nM or above. Putative SR-binding domains and the arrangement of some of the amenable targets is indicated in **Figure 4a**. H53A(+39+62) induced a low level of exon 53 skipping (**Figure 4b**), and this region was selected for subsequent AO refinement. A 25mer, H53A(+45+69) was also found to induce very weak exon skipping at 600 nM (**Figure 4c**), whereas a 31mer, H53A(+39+69), spanning the entire region covered by these 25mers was found to induce exon skipping after transfection at 10 nM (**Figure 4d**).

DISCUSSION

The concept of exon skipping to address DMD mutations is gaining considerable attention as a potential therapy for this devastating condition. Significant progress in this field is leading to clinical trials to demonstrate safety and proof of principle.[18]

Table 1 Sequences of 2′-*O*-methyl AOs used in this study

Nomenclature	Sequence (5′–3′)	Size (bp)	% G:C content
H16A(−17+08)	UUU AAA ACC UGU UAA AAC AAG AAA G	25	24
H16A(−12+19)	CUA GAU CCG CUU UUA AAA CCU GUU AAA ACA A	31	32
H16A(−06+19)	CUA GAU CCG CUU UUA AAA CCU GUU A	25	36
H16A(−06+25)	UCU UUU CUA GAU CCG CUU UUA AAA CCU GUU A	31	32
H16A(−07+13)	CCG CUU UUA AAA CCU GUU AA	20	35
H16A(+01+25)	UCU UUU CUA GAU CCG CUU UUA AAA C	25	32
H16A(+06+30)	CUU UUU CUU UUC UAG AUC CGC UUU U	25	32
H16A(+11+35)	GAU UGC UUU UUC UUU UCU AGA UCC G	25	36
H16A(+12+37)	UGG AUU GCU UUU UCU UUU CUA GAU CC	26	36
H16A(+45+67)	GAU CUU GUU UGA GUG AAU ACA GU	23	35
H16A(+87+109)	CCG UCU UCU GGG UCA CUG ACU UA	23	52
H16A(+92+116)	CAU GCU UCC GUC UUC UGG GUC ACU G	25	56
H16A(+105+126)	GUU AUC CAG CCA UGC UUC CGU C	22	54
H16D(+11−11)	GUA UCA CUA ACC UGU GCU GUA C	22	45
H16D(+05−20)	UGA UAA UUG GUA UCA CUA ACC UGU G	25	36
H51A(−01+25)	ACC AGA GUA ACA GUC UGA GUA GGA GC	26	50
H51A(+61+90)	ACA UCA AGG AAG AUG GCA UUU CUA GUU UGG	30	40
H51A(+66+90)	ACA UCA AGG AAG AUG GCA UUU CUA G	25	43
H51A(+66+95)	CUC CAA CAU CAA GGA AGA UGG CAU UUC UAG	30	40
H51A(+111+134)	UUC UGU CCA AGC CCG GUU GAA AUC	24	50
H51A(+175+195)	CAC CCA CCA UCA CCC UCU GUG	21	62
H51A(+199+220)	AUC AUC UCG UUG AUA UCC UCA A	22	36
H51D(+08−17)	AUC AUU UUU UCU CAU ACC UUC UGC U	25	32
H51D(+16−07)	CUC AUA CCU UCU GCU UGA UGA UC	23	43
H53A(−07+18)	GAU UCU GAA UUC UUU CAA CUA GAA U	25	28
H53A(−12+10)	AUU CUU UCA ACU AGA AUA AAA G	22	23
H53A(+23+47)	CTG AAG GTG TTC TTG TAC TTC ATC C	25	44
H53A(+39+62)	CUG UUG CCU CCG GUU CUG AAG GUG	24	58
H53A(+39+69)	CAU UCA ACU GUU GCC UCC GGU UCU GAA GGU G	31	52
H53A(+45+69)	CAU UCA ACU GUU GCC UCC GGU UCU G	25	52
H53A(+124+145)	UUG GCU CUG GCC UGU CCU AAG A	22	55
H53A(+151+175)	GUA UAG GGA CCC UCC UUC CAU GAC U	25	52
H53D(+09−18)	GGU AUC UUU GAU ACU AAC CUU GGU UUC	27	37
H53D(+14−07)	UAC UAA CCU UGG UUU CUG UGA	21	38
M23D(+07−18)	GGC CAA ACC UCG GCU UAC CUG AAA U	25	52
M23D(+02−18)	GGC CAA ACC UCG GCU UAC CU	20	60
M23D(+12−18)	GGC CAA ACC UCG GCU UAC CUG AAA UUU UCG	30	50
M23D(+07−23)	UUA AAG GCC AAA CCU CGG CUU ACC UGA AAU	30	43

AO, antisense oligonucleotide. AO nomenclature is based upon target species (H, human, M, mouse), exon number, and annealing coordinates as described by Mann *et al.*[27] The number of exonic nucleotides from the acceptor site is indicated as a positive number, whereas intronic bases are given a negative value. For example, H16A(−06+25) refers to an AO for human dystrophin exon 16 acceptor region, at coordinates 6 intronic bases from the splice site to 25 exonic bases into exon 16. The total length of this AO is 31 nucleotides and it covers the exon 16 acceptor site.

Exon 51 has been chosen for the "first time in human" studies, as removing this exon could restore the reading frame in a substantial number of DMD patients who have deletions in the major mutation hotspot of the dystrophin gene.[19] These trials will rely on direct intramuscular injections to deliver the AOs into dystrophic muscle, in sufficient amounts to restore dystrophin expression in a localized area. If no adverse events are reported, and molecular testing confirms exon 51 exclusion

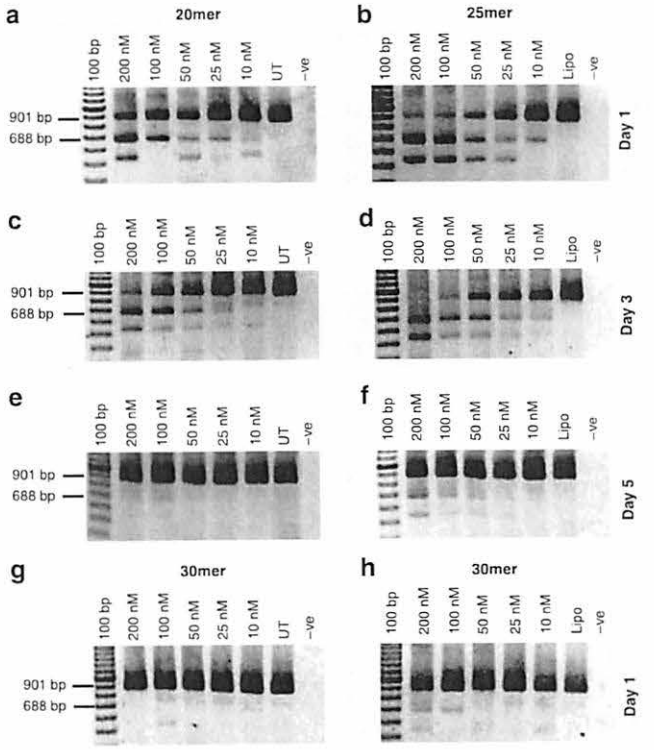

Figure 1 RT-PCR analysis showing exon skipping induced by AOs directed at mouse dystrophin exon 23. The intact dystrophin transcript is represented by a 901 bp product, and the shorter product (688 bp) corresponds to transcripts excluding exon 23. A 542 bp product that corresponding to skipping of both exons 22 + 23 is evident in some lanes and has been reported previously.[17] (**a**, **c**, and **e**) Levels of exon skipping induced by the 20mer, M23D(+02−18) at days 1, 3, and 5 post-transfection. (**b**, **d**, and **f**) Exon skipping induced by the 25mer AO, M23D(+07−18) at days 1, 3, and 5 post-transfection. (**g** and **h**) Levels of exon skipping induced by the 30mers M23D(+12−18) and M23D(+07−23), respectively, 24 h post-transfection. Untreated controls are indicated as UT, transfection reagent controls are indicated as Lipo (Lipofectin), and PCR-negative controls are indicated −ve.

and dystrophin production, subsequent trials will be initiated to evaluate exon skipping, using systemic AO delivery. Additional trials will be required to address other targets within the dystrophin gene transcript, as one limitation of AO-induced exon skipping is that this therapy must be customized for each distinct dystrophin mutation. Consequently, a panel of AOs are required to address mutations across the dystrophin gene, and it is essential that the most effective compounds are taken to the clinic.

We classify an effective AO as one that induces strong, consistent, and sustained exon skipping, preferably after administration at concentrations in the range of 10–50 nM, as assayed in myogenic cells *in vitro*. This classification is somewhat arbitrary in that many of the AOs developed in our laboratory can induce substantial levels of exon skipping, but only after administration at concentrations of 200 nM or higher. The more efficacious AOs can induce sustained and pronounced exon skipping when applied at lower concentrations. The 20 and 25mers, M23D(+02−18) and M23D(+07−18), induced similar levels of murine dystrophin exon 23 skipping after *in vitro* transfection at concentrations of 200 nM or higher. However, the longer AO must be regarded as the preferred compound as it is effective at lower concentrations and shows extended duration of induced exon skipping. It would also be preferable to use AOs at the lowest possible concentration to minimize the cost of treatment, extend the therapeutic action of exon skipping, and also reduce the risk of non-specific effects, which is of particular relevance with certain AO chemistries (for a review see refs. 20,21).

We have used normal human myogenic cells to aid in the design of AOs that target dystrophin exons, as this system allows all of the dystrophin exons to be examined using the natural human splicing machinery. The humanized DMD mouse[22] has been proposed as a model in which to design and evaluate AOs for the treatment of DMD. We urge caution in manipulating human dystrophin gene expression on a background of mouse splicing machinery. In addition, modifying normal dystrophin expression also sets a higher "bench mark" for inducing and maintaining out-of-frame transcripts. Removal of certain exons from the normal dystrophin transcript will mimic DMD-associated gene deletions, disrupt the reading frame, and render the induced transcripts susceptible to rapid turnover through nonsense-mediated decay. In some dystrophic muscle, the levels of dystrophin mRNA are reportedly a fraction of those in normal muscle.[23] If only low levels of exon skipping could be induced in dystrophic cells, there may be insufficient mRNA to produce therapeutic levels of dystrophin. We would anticipate that appropriately induced exon skipping should by-pass protein-truncating mutations, restore the reading frame, and rescue the transcript from nonsense-mediated decay. We would then expect in-frame dystrophin transcripts to accumulate, thus increasing dystrophin expression, although this has yet to be confirmed.

We have found that designing an AO to induce efficient exon skipping can be a unique challenge for each individual exon. In some cases, exon removal was easily and efficiently induced by targeting a variety of motifs. Previously, we and others showed that exon 19 skipping could be induced at high levels by targeting either acceptor, donor, or ESE sites with AOs that varied in length from 12 to 31 nucleotides.[24–26] A 31mer was the most efficient at inducing exon 19 skipping and shorter AOs that annealed within the 31mer coordinates showed reduced capacity to dislodge this exon from the mRNA, a trend most pronounced at lower transfection concentrations.[24] This provided one of the first examples showing that longer AOs tend to be more effective at inducing targeted exon skipping.

We have previously demonstrated that refinement in AO design directed at the donor splice site of murine dystrophin exon 23 could result in enhanced exon skipping.[12,17,27,28] The M23D(+02−18) had been regarded as our optimal compound, until this report in which we directly compared M23D(+02−18) with the longer M23D(+07−18), and found the latter induced enhanced exon 23 skipping. Further increases in AO length, prompted by studies addressing some human dystrophin targets, were found to be counter-productive with respect to mouse dystrophin exon 23 skipping. The longer AOs, M23D(+12−18) and M23D(+07−23), were much less

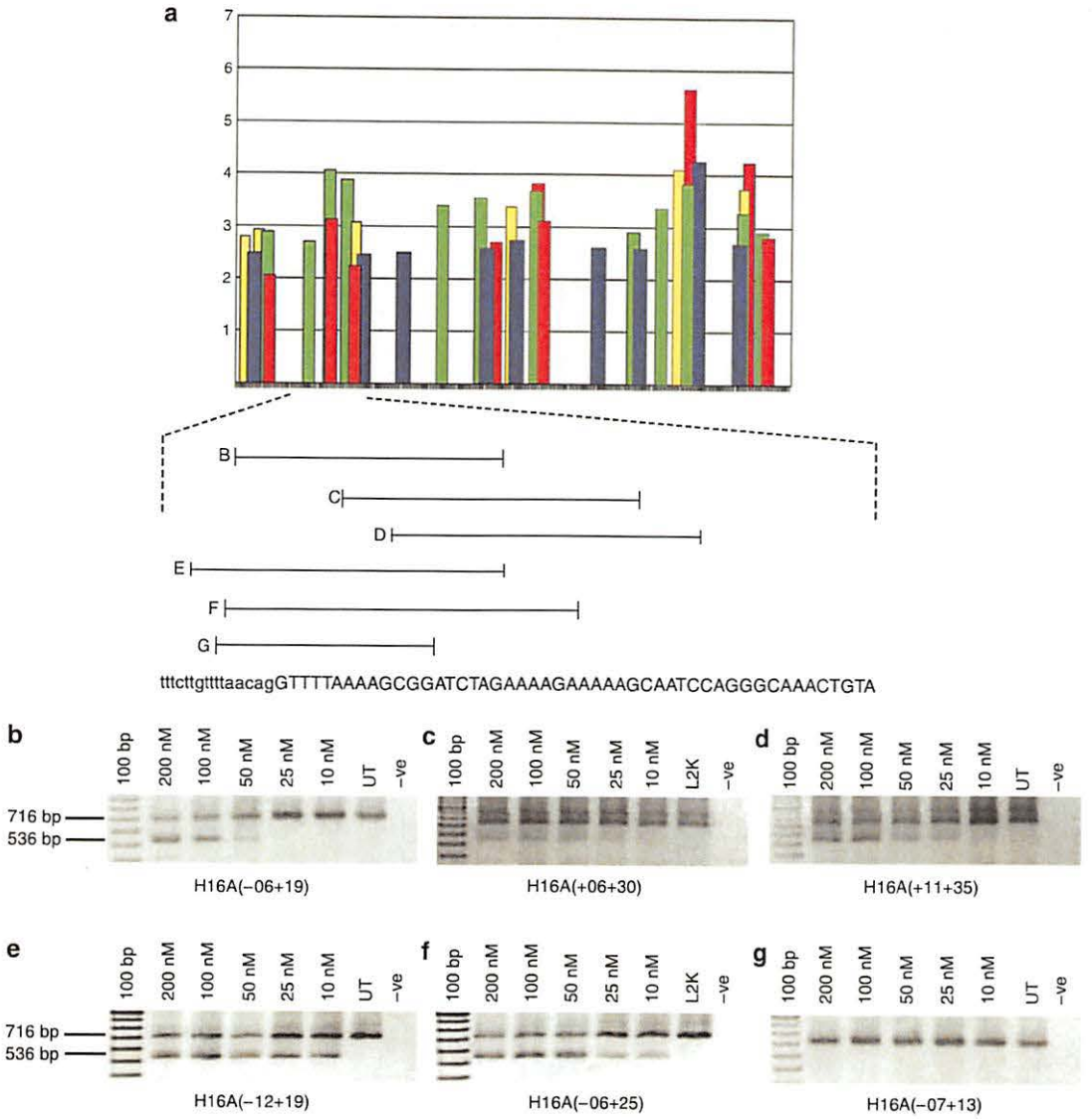

Figure 2 Induction of exon 16 skipping in the human dystrophin gene transcript. (**a**) Putative SR-binding sites for human dystrophin exon 16, as predicted by ESEfinder 2.0, SF2/ASF (red), SC35 (blue), SRp40 (green), and SRp55 (yellow).[30] The nucleotide sequence analyzed by ESEfinder included exons 16 and 50 flanking intronic bases (*X* axis). The acceptor splice site and flanking sequence targeted by the AOs is expanded. (**b–g**) RT-PCR of exon skipping induced by AOs as specified, 24 h after transfection. The intact transcript is represented by a product of 716 bp, whereas the transcript product missing exon 16 is 536 bp. Untreated controls are indicated as UT, transfection reagent controls are indicated as L2K (Lipofectamine 2000), and PCR-negative controls are indicated −ve.

effective at removing exon 23 from the mature dystrophin mRNA, and this may reflect influences of secondary structure of the dystrophin mRNA in that area.

The program Mfold[29] was used to analyze potential secondary structures occurring in the AOs, as these 2′-*O*-methyl compounds are regarded as RNA-like. *In silico* analysis of AO folding indicated the same potential self-annealing (three G:Cs and one G:U) in the two AOs that induced strong mouse dystrophin exon 23 skipping, M23D(+02−18) and M23D(+07−18), and one of the 30mers, M23D(+12−18). The other 30mer, M23D(+07−23) that induced slightly better exon 23 skipping than M23D(+12−18), contained one additional A:U pair in the four nucleotide duplex (data not shown); hence, we consider AO secondary structure an unlikely factor contributing to the inability of the 30mers to induce exon skipping.

Human dystrophin exons 16, 51, and 53 are examples in which induction of efficient exon skipping was not readily achieved. We found no definitive method to predict amenable sites within the pre-mRNA that, when targeted with an AO, would ensure efficient exon excision. For example, ESEfinder[30] predicted a cluster of strong SR-binding sites (based on threshold score for each of the four SR proteins) near the 3′ end of exon 16, adjacent to the donor splice site. ESEfinder includes a caveat

Table 2 A summary of AO efficiency with respect to targeted exon skipping and predicted SR-binding sites—ESEfinder 2.0[30]

Nomenclature	Skipping efficiency	SF2/ASF	SC35	SRp40	SRp55
H16A(−17 +08)	+	3.12	–	4.05/3.87/2.69	–
H16A(−12+19)	++	3.13/2.24	2.46	4.06/3.87	3.07
H16A(−06+19)	+	3.13/2.24	2.46	4.06/3.87	3.07
H16A(−06+25)	++	3.13/2.24	2.46	4.06/3.87	3.07
H16A(−07+13)	–	3.13	–	4.06/3.87	3.07
H16A(+01+25)	–	2.24	2.45	3.87	3.06
H16A(+06+30)	+	2.24	2.45	–	–
H16A(+11+35)	+	–	2.45	–	3.06
H16A(+12+37)	–	–	2.45/2.49	–	–
H16A(+45+67)	–	–	–	3.39	–
H16A(+87+109)	+	3.82/3.11	2.74	3.67	3.39
H16A(+92+116)	–	3.82/3.11	–	3.67	–
H16A(+105 +126)	–	–	–	–	–
H16D(+11−11)	–	5.63	4.26	3.82	4.10
H16D(+05−20)	–	5.63	4.26	3.82	–
H51A(−01+25)	+	3.49/2.05	2.78	2.72/3.08/3.98	–
H51A(+61+90)	++	2.16	–	–	–
H51A(+66+90)	++	–	–	–	–
H51A(+66+95)	++	–	–	–	–
H51A(+111+134)	–	2.56	3.05/2.58	3.55/2.71	–
H51A(+175+195)	–	5.01/2.68	–	3.94/3.55	2.91
H51A(+199+220)	–	2.24	–	2.88	2.81
H51D(+08−17)	–	3.09	–	–	–
H51D(+16−07)	+	3.09	–	–	–
H53A(−7+18)	–	–	3.07	3.10	–
H53A(−12+10)	–	–	3.07	3.10	–
H53A(+23+47)	+/−	–	–	3.19/2.94	–
H53A(+39+62)	+/−	3.08/2.48	–	3.19	–
H53A(+39+69)	++	3.08/2.48	–	3.19	–
H53A(+45+69)	+	3.08	–	3.19	–
H53A(+124+145)	–	2.55/2.2	4.04	3.4/3.0/2.89	–
H53A(+151+175)	+/−	2.06	5.43	–	–
H53D(+09−18)	+/−		3.81	–	–
H53D(+14−07)	+/−	3.40	3.81	3.90	2.90

AO, antisense oligonucleotide. The threshold scores predicted here by ESEfinder are shown for each AO and additionally, correspond to peaks illustrated in **Figure 2a** for exon 16, and **Figure 4a** for exon 53.

stating "the presence of a high score motif does not necessarily identify that sequence as an ESE in its native context. For example, a nearby silencer element may prevent the SR protein from binding". Nevertheless, this *in silico* prediction provided a useful starting point and suggested the exon 16 donor region was an appropriate target for AOs to influence splicing and promote exon exclusion. Masking these domains, in addition to the donor splice site, with several different AOs failed to induce any detectable exon 16 skipping. However, directing AOs at the beginning of this exon induced strong and sustained exon skipping, but only after transfection with AOs of adequate length. Two 31mers, three 25mers, and a 20mer annealed to the similar overlapping coordinates within human dystrophin exon 16 and all, except the shortest AO H16A(−07 + 13), induced some exon 16 skipping. Exon 16 removal was never observed after transfection with the 20mer, H16A(−07 + 13). Although there was no evidence of any AO synthesis problems with this 20mer, a second AO was prepared, evaluated, and also found to be ineffective at inducing detectable exon 16 skipping.

Oligonucleotide folding was again analyzed using Mfold,[29] and there was no apparent correlation between potential secondary structures and the ability of a compound to induce

exon skipping. For example, H16A(−12+19), which induced optimal exon 16 removal, had the potential to self-anneal and form a six A:U duplex, whereas the shorter, inactive H16A(−07+13) could only form a four base A:U duplex (data not shown). This four base A:U duplex was also found in the 25mer H16A(−06+19) that induced substantial exon skipping. It is possible that the length and low G:C content of H16A(−07+13) may have contributed to the inability to anneal to the target with sufficient affinity to prevent assembly of splicing factors.

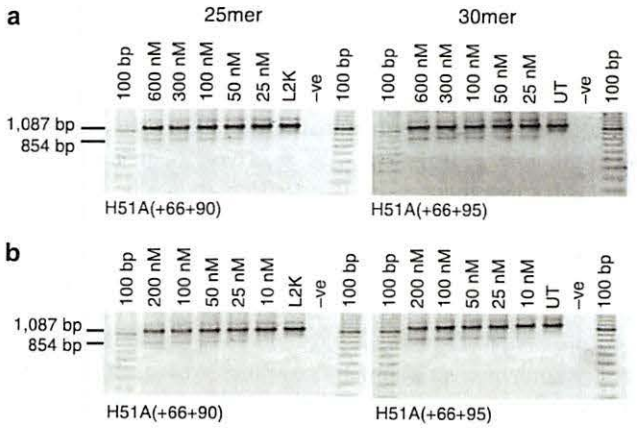

Figure 3 RT-PCR analysis of total RNA from transfected human cells showing exon skipping induced by AOs H51(+66+90) and H51(+66+95) directed at human dystrophin exon 51. The full-length product is 1,087 bp, whereas the product excluding exon 51 is 854 bp. (**a**) Transfection at concentrations ranging from 600 to 25 nM. (**b**) Transfection at concentrations ranging from 200 to 10 nM. Untreated, transfection reagent, and PCR-negative controls are indicated as UT, L2K, and −ve.

The dystrophin pre-mRNA of exon 16, along with flanking intronic sequence, was also analyzed by Mfold. In several predicted structures, there were putative loop-outs that were targeted by the two 31mers, the 25mer H16A(−06+19) and the 20mer H16A(−07+13). The 20mer annealed precisely to both putative loop-outs, whereas the longer AOs annealed to flanking sequences that were predicted to assume a duplex conformation (data not shown). Again, there was no obvious correlation between binding of the AOs to single-stranded RNA and the ability to induce exon 16 skipping. Limitations of Mfold prediction include analysis of a static segment of sequence, the length of which is somewhat arbitrarily inserted into the program, rather than a nascent gene transcript extruded from the carboxy terminal domain of RNA Pol II, where a complex of proteins and ribonuclear particles assemble on the emerging pre-mRNA.[31,32]

In the example of exon 16 skipping, we clearly demonstrated that the longer AOs were more efficient at inducing exon

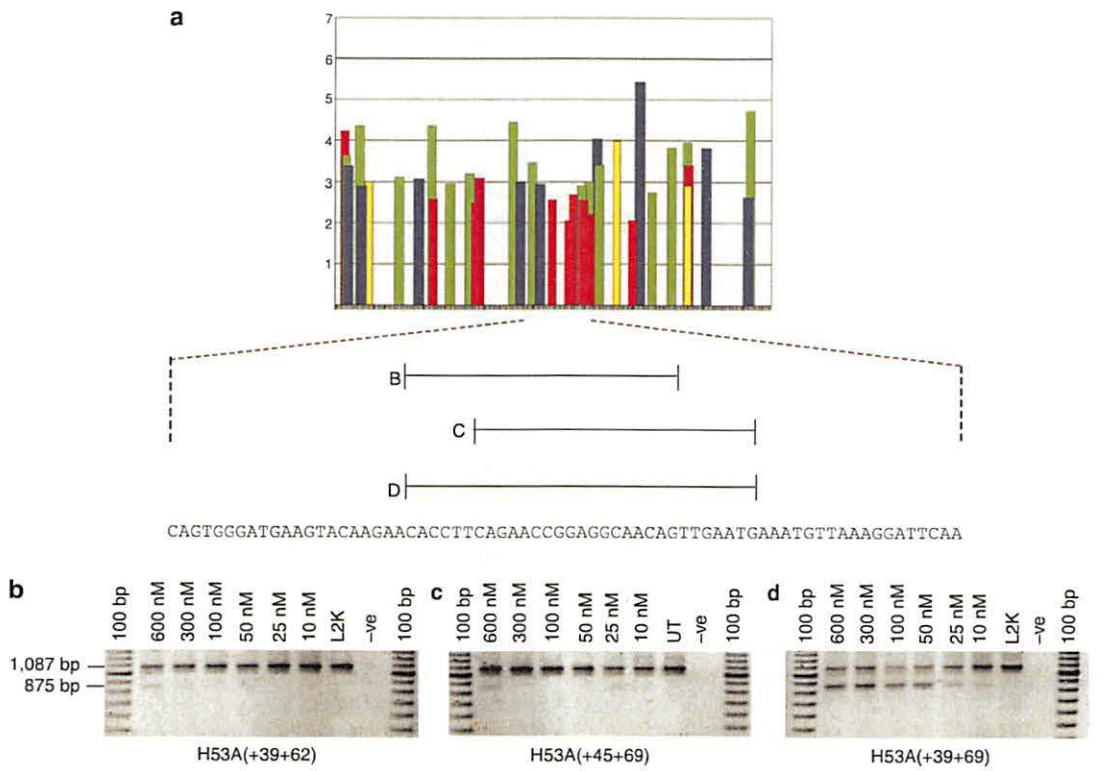

Figure 4 Induction of exon 53 skipping in the human dystrophin gene transcript. (**a**) SR-binding sites for human dystrophin exon 53 as predicted by ESEfinder 2.0, SF2/ASF (red), SC35 (blue), SRp40 (green), and SRp55 (yellow).[30] The nucleotide sequence analyzed included the exon 53 sequence and 50 flanking intronic bases. An expanded view shows annealing sites of AOs. (**b–d**) RT-PCR analysis of exon skipping induced by these AOs. The full-length transcript is 1,087 bp, whereas the transcript with exon 53 missing is 875 bp. Untreated, transfection reagent, and PCR controls are indicated as UT, L2K, and −ve.

skipping than overlapping shorter counterparts. These results suggest that the most effective compounds to take to the clinic would be either of the 31mers. In the case of targeting exon 51, this trend was still evident in that some of the longer AOs of 25–30 nucleotides induced higher levels of exon skipping than shorter compounds. However, in this particular example, there was no major difference in efficacy between the overlapping 25 and 30mers. Neither of these AOs targeted any obvious motif predicted to influence splicing, and it is possible that, as yet unidentified factors or secondary structures important in the splicing process were disrupted by the AO annealing. When targeting exon 51, other factors including the ease and cost of AO production may become more significant in the final selection of the optimal compound.

Ease and cost of AO production are not relevant when selecting the preferred compound for exon 53-induced skipping. Overlapping 25mers were only able to induce very low levels of exon 53 skipping, whereas the 31mer induced consistent exon skipping at transfection concentrations as low as 10 nM. Mfold predictions of AO folding indicated that the 31mer H53A(+39+69) could form the same imperfect six base duplex found in H53A(+39+62). The shorter compound has a higher G:C content of 58%, compared to 52% of the 31mer, so it would appear that the strength of annealing is unlikely to be an issue in this example.

There are a number of factors that will influence and effect AO efficacy, including nucleotide sequence. Studies by Matveeva *et al.*[33] have shown certain sequence motifs are associated with poor antisense activity in gene transcript downregulation. It was of interest that these data are not consistent with that for AOs effective at inducing exon skipping. The motif AAAA, which is associated with poor antisense activity for downregulation of gene transcripts, occurs twice in the very effective AO for exon 16, H16A(−12+19) (**Table 1**). Other factors affecting AO activity include length and chemistry of the modified bases and the nature of the backbone. The modified bases and backbone will greatly impact on the stability of the AO within the cell, and will be crucial to its sustained activity. AOs with the phosphorothioate backbone and 2′-*O*-methyl modified sugars are subject to degradation by nucleases, but at greatly reduced rates.[34,35] It has been reported that most AO degradation arises primarily from 3′ to 5′ exonucleases, and we have shown that modified linkages at the 3′ AO terminus can increase and extend exon skipping induction, presumably through increased AO stability.[36] It is possible that AOs of greater length may persist longer in the nucleus, thereby conferring activity for an extended period, relative to shorter compounds. As it is presumed that AOs exert their influence by steric hindrance of the splicing machinery, the longer AOs could more effectively block regions essential to the splicing process. It is likely that both these factors influence AO efficiency *in vivo*. Regardless of the mechanism(s), the longer AOs tend to induce more sustained and prolonged exon skipping, but on an exon-by-exon basis, and to date, this has been determined empirically.

It has been proposed that the use of longer AOs may reduce specificity and could induce undesirable exclusion of exons other than the target.[37] Although this possibility cannot be discounted, the conjecture is somewhat pointless if sub-optimal, shorter AOs have to be used at much higher concentrations to induce targeted exon removal. With respect to exon 16, we would estimate the optimal 31mer to be several fold more effective than the best 25mers, based on titration studies where similar levels of exon skipping were induced at 10–25 nM with H16A(−12+19) and between 50 and 100 nM with H16A(−06+19). If the optimal AO can induce substantial levels of exon 16 skipping after application at 10 nM, the risk of adverse events associated with the AO chemistry or off-target effects should be reduced. Annealing to homologous sequences cannot be discounted and we previously demonstrated that an AO with up to five mismatched bases could induce low levels of exon 19 skipping, but only when applied at high concentrations.[24] The risk of cross-annealing to related sequences should be minimized if the AOs were only present at low concentrations. Even if there was some crossreaction with homologous sequences, one would anticipate that unless that region contained a splice site, or was involved in initiation of translation, no effects on gene expression would be observed. We have shown in this report that subtle changes in the annealing site of the intended target can play a major role in the efficacy of that compound to modify pre-mRNA processing. The possibility of inadvertently masking another amenable site in a homologous transcript, and altering processing and expression of that RNA strand, must be regarded as remote.

Simply designing an AO of 30 nucleotides will not guarantee induction of exon skipping, and in some cases may be counter-productive, as found when targeting the murine dystrophin exon 23 donor splice site. Our AO designing strategy now involves evaluating AOs of 25 bases, designed to acceptor, donor, and putative ESE motifs, in the primary screen, involving several different *in vitro* transfection concentrations. Subsequent compounds of 25–30 nucleotides are then designed and prepared to those motifs identified in the splicing of the target exon. In the four examples described in this report, amenable sites to redirect dystrophin splicing were identified at the acceptor (human exon 16), 66–95 bases within the 233 base exon 51, 39–69 bases within the 212 base long exon 53, and at the donor splice site of murine exon 23.

In summary, *in silico* predictions may aid in the initial design of AOs to induce targeted exon skipping. There was a trend for the more efficient AOs to target multiple SF2/ASF, SRp40 and SC35 SR motifs, although this was not absolute (**Table 2**). We suggest that refinement of AO design and identification of amenable sites should be carried out empirically, rather than relying on *in silico* predictions of RNA secondary structure, the masking of obvious splice sites, or predicted ESE motifs. The length of the AO has emerged as a major parameter, AOs of 25–31 nucleotides outperform shorter compounds. In one case, a 25mer was found to be far more effective than overlapping 30mers and a 20mer. In situations where there is no major difference in efficacy between a 25mer and a 31mer, other considerations such as cost and ease of AO production would then become more relevant.

MATERIALS AND METHODS

AO design and synthesis. AOs were synthesized on an Expedite 8909 Nucleic acid synthesizer using the 1 μmol thioate synthesis protocol. Phosphoramidites for synthesis of 2′-*O*-methyl AOs were purchased from Glen Research (Sterling, VA). Columns were prepared using a DNA synthesis column kit (Applied Biosystems, Melbourne, Australia) with 2′-*O*-methyl CPG supports from Glen Research. AOs were cleaved overnight at room temperature with ammonium hydroxide (Sigma, Melbourne, Australia) and were desalted on NAP-10 columns (Amersham, Melbourne, Australia). Gram quantities of MD23(−07 + 18) were obtained from Avecia (Grangemouth, UK).

AOs were synthesized to anneal to splicing motifs at the intron:exon boundaries, as well as ESE motifs predicted by the web-based application, ESEfinder, http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=12824367.[30] **Table 1** lists the AOs evaluated, the nomenclature indicates target species and annealing coordinates.

Culture and transfection—H-2K^b-tsA58 (H2K) mdx myoblasts. *H2K-Mdx* myoblasts[38] were cultured as described by Mann *et al.*[17] AOs were transfected with Lipofectin:AO at 2:1 w:w ratio, 48 h after seeding. Lipofectin was used according to the manufacturer's instructions (Invitrogen, Melbourne, Australia). All transfections were duplicated and repeated three times to ensure results were reproducible.

Culture and transfection—primary human myoblasts. Primary human myoblasts were prepared from patient biopsies[39] supplied by the Department of Neuropathology, Royal Perth Hospital after informed consent. The patient muscle samples were minced with scissors in a few drops of phosphate-buffered saline. The cell slurry was then placed in 2 ml/g (tissue) DMEM (Gibco-Invitrogen, Melbourne, Australia) with 2.4 U/ml of dispase, collagenase, 1% (w/v) (Roche Molecular Biochemicals, Melbourne, Australia), $CaCl_2$ at 2.4 mM, and the suspension was maintained at 37°C for 30–45 min with occasional mixing by pipette. The cell suspension was then centrifuged at 350 *g* to sediment the cells. The cells were washed in DMEM and re-suspended in growth medium, Hams F10 with 20% fetal calf serum, 0.5% chick embryo extract (Jomar Diagnostics, Stepney, South Australia), with basic fibroblast growth factor (human, recombinant) (Invitrogen), 10 U/ml penicillin (Invitrogen), 10 μg/ml streptomycin (Invitrogen), and 250 ng/ml amphotericin B (Sigma, Melbourne, Australia), and were cultured at 37°C with 5% CO_2. Re-suspended cells were pre-plated onto uncoated plates to remove fibroblasts; myoblasts were plated onto 100 μg/ml Matrigel- (Australian Biosearch, Perth, Australia) coated flasks and incubated at 37°C with 5% CO_2. The growth media was changed after 3 days. Cells are frozen or sub-cultured when ~70% confluent.

For transfection experiments, tissue culture plates (24 wells) were pre-treated with 50 μg/ml poly D-lysine and 100 μg/ml Matrigel (Australian Biosearch, Perth, Australia). After proliferation, the myoblasts were treated with trypsin and seeded at 2.5×10^4 cells/well in a 24-well plate with DMEM and 5% horse serum (Invitrogen), to encourage differentiation. Primary human myotubes were transfected in Opti-MEM (Invitrogen), 48 h after seeding, with Lipofectamine 2000 (L2K):AO at 1:1 w:w ratio according to the manufacturer's instructions (Invitrogen). For each experiment, transfections were repeated three times to ensure reproducibility of results.

RNA extraction and RT–PCR. RNA was extracted 1, 3, 5, or 7 days after transfection as indicated, using Trizol according to the manufacturer's instructions (Invitrogen). Primer sets for reverse transcription–PCR (RT–PCR) analysis of AO-induced exon skipping were chosen to amplify fragments of the dystrophin gene transcript with several exons flanking the target exon. This should minimize preferential amplification of smaller products and also allow examination of any effects on flanking exons. RT–PCR was performed on 100 ng total cellular RNA using Titan One-Tube RT–PCR system (Roche Molecular Biochemicals). cDNA was synthesized for 30 min at 48°C, followed by 30 cycles of amplification with cycling conditions of 94°C for 30 s, 55°C for 1 min, and extension at 72°C for 2 min. Primer sequences used for amplification of the mouse transcript are described by Mann *et al.*[17] The primary amplification of exon 16 used primers that anneal to exon 9 forward (cgattcaagagc tatgcctac) and exon 18 reverse (gcgagtaatccagctgtgaag). Secondary amplification was carried out with primers, 12 forward (taatggatctcca gaatcag) and 17 reverse (ccgtagttactgtttccatta). Primary amplification of exons 51 and 53 was performed with exon 47 forward primer (gctcccataagcccagaagagc) and exon 58 reverse primer (ctcctggtagagtttctc tag). Secondary amplification was carried out with exon 47 forward (tgtggttatctcctattagg) and exon 58 reverse primers (ctcctggtagagtttctc tag). One microliter of the RT–PCR product was used as the target for secondary amplification following 6-min incubation at 94°C and 30 cycles using AmpliTaq-Gold (Applied Biosystems, Melbourne, Australia). PCR products were fractionated on 2% Tris-acetate EDTA buffer agarose gel and stained with ethidium bromide. Images were recorded with a Chemi-Smart 3000 gel documentation system (Vilber Lourmat, Marne La Vallee).

Sequencing. The RT–PCR products were re-amplified by bandstab[40] and purified using Ultraclean PCR clean up DNA purification kit from Mo-bio (Geneworks, Adelaide, Australia). The purified products were sequenced using an Applied Biosystems 377 DNA sequencer and BigDye V3.1 terminator chemistry (Applied Biosystems). Sequencing PCR conditions were 25 cycles of 96°C for 30 s, 50°C for 30 s, and 60°C for 4 min.

ACKNOWLEDGMENTS

The authors received funding from aktion benni and co e.V., Germany, the National Institutes of Health (RO1NSO44146-02), the Muscular Dystrophy Association USA (MDA3718), the National Health and Medical Research Council of Australia (303216), and the Medical and Health Research Infrastructure Fund (Western Australia). The technical assistance of B Gebski is acknowledged.

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EXHIBITS 56-57 REDACTED IN THEIR ENTIRETY

EXHIBIT 58

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

W.R. GRACE & CO.-CONN., Plaintiff, v. ELYSIUM HEALTH, INC., Defendant.	C.A. No. 20-1098-GBW-JLH **FILED UNDER SEAL**

MEMORANDUM ORDER

Plaintiff W.R. Grace & Co.-Conn. ("Grace") accuses Defendant Elysium Health, Inc. ("Elysium") of infringing U.S. Patents Nos. 10,323,058 ("the '058 patent") and 10,233,207 ("the '207 patent") (collectively, the "Form I patents"), and U.S. Patent No. 10,189,872 ("the '872 patent" or "the Form II patent").[1] D.I. 1 ¶ 1. On May 5, 2022, Elysium filed an Amended Answer and Counterclaims to Grace's Complaint (the "Answer"). D.I. 113. Here, Elysium raises claims of inequitable conduct against Grace, asserting that the Asserted Patents be deemed invalid. *Id.*

The Court will address (1) Grace's *Daubert* motions, D.I. 206, D.I. 207, D.I. 208, D.I. 209, D.I. 210, (2) Elysium's *Daubert* motions, D.I. 186, D.I. 187, D.I. 188, (3) Grace's motions for summary judgment, D.I. 191, D.I. 192, D.I. 193, D.I. 194, and (4) Elysium's motions for summary judgment, D.I. 197, D.I. 198, D.I. 199, D.I. 200.

I. BACKGROUND

The Asserted Patents claim crystalline Forms I and II of nicotinamide riboside chloride ("NRCl"). *See* D.I. 1, Ex. A (the '207 patent) at claim 1; Ex. B (the '058 patent) at claim 1; Ex. C

[1] All three patents, the '058 patent, the '207 patent, and the '872 patent, will be collectively referred to as the "Asserted Patents."

(the '872 patent) at claim 1. The Court construed (a) "crystalline Form I of [NRCl] according to formula I" in the '058 patent and the '207 patent as "[c]rystalline Form I of [NRCl], according to Formula I, which can be identified by one or more of the analytical methods described in the specification" and (b) "crystalline Form II of [NRCI]" in the '872 patent as "[c]rystalline Form II of [NRCl], which can be identified by one or more of the analytical methods described in the specification[.]" D.I 109 at 1.

II. *DAUBERT* MOTIONS

Grace moves to exclude the (1) the testimony of Robert Armitage, D.I. 206, (2) the opinions and testimony of Dr. Robert Perni and Dr. Robert Steed, in part, for allegedly improperly opining on states of mind and legal standards, D.I. 207, (3) the testimony and opinions of Dr. Robert Perni in their entirety, D.I. 208, (4) the testimony and opinions of Alexander Clemons, in part, concerning the topics of royalty rates and non-infringing alternatives, D.I. 209, and (5) the testimony and opinions of Dr. Ryan Dellinger, in part, D.I. 210. Elysium moves to exclude the testimony and opinions of W.R. Grace's crystallography expert Dr. Aeri Park, D.I. 186, and the testimony and opinions offered by W.R. Grace's damages expert Kimberly Schenk for alleged failure to apportion damages (1) by batch, and (2) by patent. D.I. 187; D.I. 188. The Court will address each *Daubert* motion in turn below.

A. Legal Standards

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the Supreme Court held that Federal Rule of Evidence 702 creates "a gatekeeping role for the [trial] judge" in order to "ensur[e] that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." 509 U.S. at 597, 580. Rule 702 provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the

> trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

FED. R. EVID. 702. As the Third Circuit has explained,

> Rule 702 embodies a trilogy of restrictions on expert testimony: qualification, reliability and fit. Qualification refers to the requirement that the witness possess specialized expertise. We have . . . [held] that a broad range of knowledge, skills, and training qualify an expert. Secondly, the testimony must be reliable; it must be based on the methods and procedures of science rather than on subjective belief or unsupported speculation; the expert must have good grounds for his o[r] her belief. In sum, *Daubert* holds that an inquiry into the reliability of scientific evidence under Rule 702 requires a determination as to its scientific validity. Finally, Rule 702 requires that the expert testimony . . . must be relevant for the purposes of the case and must assist the trier of fact.

Schneider ex rel. Estate of Schneider v. Fried, 320 F.3d 396, 404-05 (3d Cir. 2003) (cleaned up); *Kuhar v. Petzl Co.*, C.A. No. 19-3900, 2022 WL 1101580, at *7 (3d Cir. Apr. 13, 2022) (noting the same trilogy).

Rule 702 "'has a liberal policy of admissibility[,]'" *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008) (citation omitted); *see also United States v. Scripps*, 599 F. App'x 443, 447 (3d Cir. 2015) (same), as "the question of whether the expert is credible or the opinion is correct is generally a question for the fact finder, not the court[,]" *Summit 6, LLC v. Samsung Elecs. Co., Ltd.*, 802 F.3d 1283, 1296 (Fed. Cir. 2015). "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 596; *see Karlo v. Pittsburgh Glass Works, LLC*, 849 F.3d 61, 83 (3d Cir. 2017) (quoting *Daubert*, 509 U.S. at 596).

B. Discussion

a. Robert Armitage

At issue is the relevance of Elysium's expert on the United States Patent and Trademark Office ("USPTO" or "PTO")) patent examination practices. *See* D.I. 211 at 25; D.I. 212, Exs. 8, 10, 26. For the reasons stated below, the Court grants-in-part Grace's Motion to Exclude the opinions of Defendant's Expert Robert Armitage. D.I. 206.

"[T]his Court has a strong and consistent view with respect to the admittance of the testimony of 'patent law experts.'" *Shire Viropharma Inc. v. CSL Behring LLC,* C.A. No. 17-414, 2021 WL 1227097, at *16 (D. Del. Mar. 31, 2021) (quoting *W.L. Gore & Assocs., Inc. v. C.R. Bard, Inc.*, C.A. No. 11-515, 2015 WL 12815314, at *3 (D. Del. Nov. 20, 2015)). "It has at times permitted testimony from such experts, including with regard to inequitable conduct allegations, so long as the testimony clearly related to the ins and outs of internal PTO practices and procedures." *Id.* (internal quotations and citation omitted). "Beyond that narrow topic, however, courts have generally excluded patent law expert testimony relating to inequitable conduct largely because such testimony frequently amounts to the proffering of impermissible legal opinions." *Id.* at *16-17 (striking testimony on inequitable conduct as improper legal analysis and legal opinion). *See also PureWick Corp. v. Sage Prod., LLC*, C.A. 19-1508-MN, 2021 WL 2593338, at *1 (D. Del. June 24, 2021) ("It is the Court's function to determine the applicable legal standards" and "legal testimony on substantive issues of patent law or Patent Office procedure improperly substitutes the judgment of the expert for that of the Court.") (internal quotations and citations omitted).

Grace asserts that Mr. Armitage's testimony should be struck because testimony concerning the actions of a "competent patent professional" is irrelevant, as there are no

inequitable conduct claims against patent professionals at Grace, and Mr. Armitage applies the incorrect standard for materiality.

Mr. Armitage in his Reply Report set out his task:

> I was asked to opine on how a competent patent professional, based upon my training and experience, would undertake the identification of information of necessary materiality under the *Therasense* standard, i.e., information that necessarily must be disclosed under the "duty of disclosure," as this duty has been imposed by the USPTO and the courts, in connection with communications with the USPTO during the examination of a patent application

D.I. 212, Ex. 8 ("Armitage Reply Rpt.) ¶ 4.

Therasense, Inc. v. Becton, Dickinson & Co., provides the rule that in order to show inequitable conduct, an accused infringer must generally show (1) "that the patentee acted with the specific intent to deceive the PTO" and (2) materiality. 649 F.3d 1276, 1290 (Fed. Cir. 2011). Inequitable conduct claims are still alleged against Erik Carlson and Brett Reynolds. D.I. 225. Erik Carlson is an employee at Grace and a named inventor of the Asserted Patents. D.I. 1 ¶¶ 15-17, Exs. A-C. Regarding Mr. Reynolds, "Elysium alleges that Reynolds determined on September 25, 2018 that Grace shipped crystalline NRCl to a third party and sent or received emails related to 'patent applications' and to 'the prosecution and validity of the Grace patents' on July 30, 2018." D.I. 225 at 9. It is not clear to the Court that either Mr. Reynolds or Mr. Carlson qualify as the "competent patent professional" that Mr. Armitage seeks to opine on the actions (or inactions) of. *See* D.I. 212, Ex. 10 (Armitage Depo. Tr.) at 27:20-28:23. Furthermore, Mr. Armitage states that his "opinions are confined to how that [*Therasense*] standard would be applied by a competent patent attorney" and that he "limited [his] opinions to what subject matter the patent examiner would or would not have allowed to issue based upon what the USPTO instructs patent examiners they must do through the MPEP." D.I. 212, Ex. 8 (Armitage Reply Rpt.) ¶¶ 67, 70. Notably, neither Mr. Reynolds nor Mr. Carlson are patent attorneys or patent examiners. D.I. 258 at 2.

When addressing Grace's contention that Mr. Armitage's opinions are not relevant to Elysium's claims in this case and that the conduct of patent professionals is not "germane" to any issues in this case, Elysium asserts that such a stance "ignores the fact that Elysium's Amended Counterclaims specifically alleges that Grace's patent professionals and those working with them intentionally failed to provide material information concerning the pre-Critical Date offers to sell and sales of crystalline NR-Cl." D.I. 229 at 32. But neither Mr. Short nor Ms. Smith, the referenced "patent professionals" and those working with them, have inequitable conduct claims alleged against them. D.I. 225.

"As a general rule, expert witnesses may not testify as to the law governing a dispute or offer conclusions concerning a party's compliance with legal duties." *Brigham & Women's Hosp. Inc. v. Teva Pharms. USA, Inc.*, C.A. No. 08-464, 2010 WL 3907490, at *2 (D. Del. Sept. 21, 2010). *See also Zimmer Surgical, Inc. v. Stryker Corp.*, 365 F. Supp. 3d 466, 497 (D. Del. 2019) ("Expert testimony as to intent, motive, or state of mind offers no more than the drawing of an inference from the facts of the case ... and permitting expert testimony on this subject would be merely substituting the expert's judgment for the jury's and would not be helpful to the jury.") (quoting *Siring v. Oregon State Bd. of Higher Educ.*, 927 F. Supp. 2d 1069, 1077 (D. Or. 2013)).

"The law of this district is clear that experts in patent cases may not opine on whether a party engaged in inequitable conduct, discuss whether certain information was material to a pending patent application, or otherwise provide legal conclusions on 'substantive issues of patent law.'" *Brigham and Women's Hosp.*, 2010 WL 3907490, at *2 (citation omitted). Such substantive issues of patent law not permitted in expert testimony includes, for example, interpretations of the "on-sale" bar following the America Invents Act. *See, e.g.*, D.I. 212, Ex. 26 (Armitage Opening

Rpt.) ¶ 76 ("In my opinion, Grace would have had an expectation of some good faith, bona fide basis on which to believe that it was entitled to seek a patent[.]").

However, Mr. Armitage also discusses the practices and procedures of the PTO. *See* D.I. 212, Ex. 26 ("Armitage Opening Rpt.) Section III. The law permits experts in patent cases to offer such testimony. *Revlon Consumer Prods. Corp. v. L'Oréal S.A.*, No. 96-192, 1997 WL 158281, at *3 (D. Del. Mar. 26, 1997) (concluding that while the proffered patent law expert could testify with respect to "matters of PTO practice and procedure[,]" it would not allow him "to testify as an expert on inequitable conduct; to do otherwise would usurp the respective functions of the ... Court")).

Accordingly, Grace's motion to preclude testimony from Mr. Armitage is granted except to the extent that he explains the USPTO's practices and procedures.

b. Dr. Robert Perni and Dr. Robert Steed

Grace seeks to exclude the testimony of Dr. Robert Perni and Dr. Robert Steed to the extent that the experts opine on "states of mind and legal standards." D.I. 207. For the reasons discussed below, the Court grants-in-part, denies-in-part Grace's motion to exclude such testimony.

Generally, "[e]xpert witnesses are not 'permitted to testify ... regarding [a party's] intent, motive, or state of mind, or evidence by which such state of mind may be inferred.'" *AstraZeneca LP v. Tap Pharm. Prod., Inc.*, 444 F. Supp. 2d 278, 293 (D. Del. 2006) (quoting *Oxford Gene Tech., Ltd. v. Mergen Ltd.*, 345 F.Supp.2d 431, 443 (D. Del. 2004)). Upon review of the paragraphs at issue, the Court agrees that Dr. Perni and Dr. Steed, in their reports, appear to offer testimony as to Grace's state of mind related to Elysium's inequitable conduct claims. For example, Dr. Perni states:

> Documents produced by Grace demonstrate that other Grace employees, including employees involved in patent prosecution, also were aware that Grace's crystalline NR-Cl was the subject of commercial offers for sale and actual sales to ChromaDex at least one year before the priority date of the Asserted Patents and knew of its materiality to obtaining the Asserted Patents.

D.I. 213, Ex. 3 (Perni Opening Rpt.) ¶ 246 (emphasis added).

Testimony such as this goes beyond what is permissible by a technical witness and subsume the role of the fact-finder. *AstraZeneca*, 444 F. Supp. 2d at 293.

Accordingly, the Court grants Grace's motion and Drs. Perni and Steed are precluded from offering testimony about knowledge, intent, motivation, or state of mind, including but not limited to the opinions expressed in Dr. Perni's Opening Report at paragraphs 186-187, 190-193, and 221-263, and in Dr. Steed's Opening Report at paragraphs 173-174, 177-180, and 203-243.[2]

c. Dr. Robert Perni

Grace argues that Dr Robert Perni's testimony should be excluded in its entirety because he is not qualified to provide opinions on behalf of a person of ordinary skill in the art ("POSA"). D.I. 211 at 36-37. For the reasons stated below, the motion is denied.

Rule of Evidence 702 states that a witness offering an expert opinion must possesses adequate "knowledge, skill, experience, training, or education" to support his or her opinion. Qualification requires "'that the witness possess specialized expertise.'" *Allscripts Healthcare, LLC v. Andor Health, LLC*, C.A. No. 21-704-MAK, 2022 WL 3021560, at *2 (D. Del. July 29, 2022) (quoting *Pineda*, 520 F.3d at 244). The Third Circuit interprets this requirement "liberally." *Pineda*, 520 F.3d at 244. "'[A] broad range of knowledge, skills, and training qualify an expert.'" *Allscripts*, 2022 WL 3021560, at *2

[2] This is not a preclusion of all testimony found in the cited paragraphs, only a preclusion of the testimony in the paragraphs that offer testimony relating to Grace's knowledge, intent, motivation, or state of mind.

(quoting *In re Paoli*, 35 F.3d at 741). "This liberal policy of admissibility extends to the substantive as well as the formal qualifications of experts." *Pineda*, 520 F.3d at 244. Generally, experts lacking the minimum skill level of a POSA in the relevant art should be excluded. *Kyocera Senco Industrial Tools Inc. v. International Trade Commission*, 22 F.4th 1369, 1376–78 (Fed. Cir. 2022) ("To offer expert testimony from the perspective of a skilled artisan in a patent case—like for claim construction, validity, or infringement—a witness must at least have ordinary skill in the art. Without that skill, the witness' opinions are neither relevant nor reliable.")

A POSA, as defined by the parties:

> would have had a Ph.D. in chemistry, or a similar field, with 5 or more years of experience in academia or industry focused on crystallography and its methods of analysis (some of those five years could be spent as part of the Ph.D. program, for instance, but additional experience is needed to be considered a POSA). The methods of analysis can include X-ray powder diffraction ("XRPD") but are not limited to XRPD.

D.I. 212, Ex. 3 (Perni Opening Rpt.) ¶ 13.

Dr. Perni was asked to "provide opinions regarding certain matters ***from the perspective of a person of ordinary skill in the art ("POSA")*** concerning the validity" of the Asserted Patents. *Id.* ¶ 9 (emphasis added).

The issue Elysium takes with Dr. Perni's testimony is that Dr. Perni does not purport to be a POSA:

> Q: The person of ordinary skill in the art, as it has been defined, is not a synthetic chemist who has a great deal of experience in crystallization of organic compounds, right?
> A: That's correct.
> Q: So you're not going to provide opinions from the perspective of a POSA in this case, right?
> A: No.
> Q: You do not meet the qualifications as such, right?
> A: Not as written, no.

D.I. 212, Ex. 29 (Perni Depo. Tr.) at 95:3-16. *See also id.* at 90:18-92:11.

Beyond Mr. Perni's testimony, Elysium asserts that Dr. Perni objectively lacks the qualifications to testify on behalf of a POSA on the infringement and invalidity claims in the present case. D.I. 211 at 38.

Grace argues that (1) Dr. Perni is, in fact, a qualified POSA, and (2) the deposition questions that Elysium relies on were unclear. D.I. 229 at 41.

First, Dr. Perni does have a Ph.D. in chemistry and spent 30 years in research, focusing on the synthesis and crystallization of nicotinamide riboside chloride [("NRCL")]. D.I. 212, Ex. 3 (Perni Opening Rpt.) ¶ 1. While Elysium notes that Dr. Perni is "not an expert in crystallography, XRPD, or identification and characterization of crystalline forms using other analytical methods[,]" D.I. 258 at 21, he need not be in order to qualify as a POSA under the parties' definitions. Mr. Perni holds a doctorate in chemistry, decades of research experience relating to synthetic and medicinal chemistry, and "has a great deal of experience in crystallization of organic compounds." D.I. 212, Ex. 29 (Perni Depo. Tr.) 94:19-95:2. This Court finds that Dr. Perni has at least comparable qualifications to testify, and his testimony on NRCL is relevant to the case. The Court is also not inclined to disqualify Dr. Perni based on the deposition testimony presented. Indeed, Grace's criticism goes to the weight, not admissibility, of the testimony and Plaintiff is free to challenge those opinions through cross-examination of Dr. Perni at trial. *Daubert*, 509 U.S. at 596. For these reasons, Grace's motion to exclude Dr. Perni's testimony in its entirety, D.I. 207, is denied.

d. Alexander Clemons

Grace seeks to exclude the testimony of Elysium's damages expert, Alexander Clemons, in part. D.I. 209; D.I. 211 at 40-41. Specifically, Grace seeks to preclude Mr. Clemons "from

offering testimony regarding (1) his 50% reasonable royalty rate reduction opinion, and (2) his opinions regarding Elysium's allegedly available non-infringing alternatives." D.I. 211 at 40-41. The Court will review each argument in turn:

On a finding of infringement, the patentee is entitled to "damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court." 35 U.S.C. § 284. The burden of proving damages falls on the patentee. *Lucent Techs., Inc. v. Gateway*, 580 F.3d 1301, 1324 (Fed. Cir. 2009). A reasonable royalty is based not on the infringer's profit, but on the royalty that a willing licensor and a willing licensee would have agreed to at the time the infringement began. *Id.* at 1324-25 (describing the hypothetical negotiation or the "willing licensor-willing licensee" approach). The factors discussed in *Georgia-Pac. Corp. v. United States Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970) *modified sub nom. Georgia-Pac. Corp. v. U.S. Plywood-Champion Papers, Inc.*, 446 F.2d 295 (2d Cir. 1971), frame the reasonable royalty analysis. *Minerva Surgical, Inc. v. Hologic, Inc.*, C.A. No. 18-00217-JFB-SRF, 2021 WL 3048447, at *7 (D. Del. July 20, 2021).

Grace takes issue with Mr. Clemons' alleged reliance on a "rule of thumb" adjustment stemming from articles with no ties to this case, as well as relying on "vague references. . . untestable on cross-examination[.]" D.I. 211 at 41. Elysium asserts that the 50% reasonable royalty is based on "an analysis of how much it would cost Elysium to develop a new NR salt," then comparing the cost "set out in [redacted]" and finally adjusts the royalty based on factors such as exclusivity and bargaining power." D.I. 229 at 42-45.

"Assessing the comparability of licenses requires a consideration of whether the license at issue involves comparable technology, is economically comparable, and arises under comparable circumstances as the hypothetical negotiation." *Bio-Rad Lab'ys, Inc. v. 10X Genomics Inc.*, 967 F.3d 1353, 1372-73 (Fed. Cir. 2020) (citation omitted). "When relying on licenses to prove a reasonable royalty, alleging a loose or vague comparability between different technologies or licenses does not suffice." *LaserDynamics, Inc. v. Quanta Computer, Inc.*, 694 F.3d 51, 79 (Fed. Cir. 2012). Mr. Clemons' report discusses taking the market approach (after considering and ultimately rejecting other approaches based on available data), a comparability analysis with [redacted] and a review of the *Georgia-Pacific* factors. *See* D.I. 212. Ex. 27 (Clemons Rebuttal Rpt.). Grace's argument targets a factual dispute as to whether Mr. Clemons properly weighed the evidence in determining the reasonably royalty, and thus Grace's motion to preclude Mr. Clemons' testimony regarding reasonable royalty is denied. *CAO Lighting, Inc. v. Gen. Elec. Co.*, C.A. No. 20-681-GBW, 2023 WL 1930354, at *10 (D. Del. Jan. 30, 2023)

Grace next argues that Mr. Clemons should be precluded from opining on non-infringing alternatives because his testimony is (1) "too speculative" and (2) "improperly considers the accused infringing forms of NRCl to be non-infringing alternatives if one or a subset of patents might eventually be determined to be invalid or not infringed." D.I. 211 at 41-42.

"Unlike an opinion identifying a specific proposed alternative design, an opinion that there are 'many other alternative designs' is not best addressed via cross-examination or by submission to the jury because it is vague and speculative and does not 'rest[ ] on a reliable foundation." *WhereverTV, Inc. v. Comcast Cable Commc'ns, LLC*, C.A. No. 2:18 -529-JLB-NPM, 2022 WL 2751752, at *7 (M.D. Fla. July 14, 2022) (quoting *Daubert*, 509 U.S. at 597). That is not the case here. Mr. Clemons recites specific examples of noninfringing alternatives including Thorne's

NiaCel and ResveraCel products. D.I. 212, Ex. 7 (Clemons Rebuttal Rpt.) at 39-40; D.I. 229 at 45. And Grace's Reply makes it more evident that Grace's issues with Mr. Clemons' testimony on noninfringing alternatives are proper for cross-examination. *Daubert*, 509 F.3d at 596.

For the reasons above, Grace's motion to exclude portions of Alexander Clemons' testimony and opinions, (D.I. 209), is denied.

e. Dr. Ryan Dellinger

Lastly, Grace seeks to exclude Dr. Ryan Dellinger's testimony on (1) acceptable noninfringing alternatives, (2) what Elysium "would likely do," and (3) partial costs for pursuing an alternative salt form of NR. D.I. 211 at 42-43.

First, Grace asserts that Dr. Dellinger should be precluded from offering testimony because he lacks "an understanding as to what would be acceptable to customers." D.I. 211 at 43. While consumer demand is important to determining the relative market, such factors shaping that demand include "consumers' intended use for the patentee's product, similarity of physical and functional attributes of the patentee's product to alleged competing products, and price." *Grain Processing Corp. v. Am. Maize-Prod. Co.*, 185 F.3d 1341, 1355 (Fed. Cir. 1999). Elysium refutes this, arguing that "Dr. Dellinger did not offer testimony on consumers; he compared various vitamin B3 analogs and describes whether they are biological alternatives." D.I. 229 at 47 (cleaned up). Instead, Elysium clarifies that:

> Dr. Dellinger intends to testify that the body uses NR and other vitamin B3 supplements, such as niacin, nicotinamide, and NMN, to make an important cellular enzyme, NAD, and the role of another signaling protein family called sirtuins. Ex. 96, Dellinger Open. ¶¶37-39. He also will testify about NAD's role in cellular processes and recent research that vitamin B3 analogs can boost NAD levels reversing the effects of aging in cells. *Id.* at ¶¶3-4, 6, 21.

D.I. 229 at 47 n..15

Regarding Dr. Dellinger's statements on marketing, Elysium separately notes that "Elysium's marketing studies and its marketing witness confirm that "the science" is "a key driver" for the sale/marketing of Basis." D.I. 229 at 48 (citing Ex. 97, (ELY_G0023663) at -668 ("Users understand and believe the science"); Ex. 98, Marcotulli at 18:9-19:5; 46:1-15; *see* Ex. 96, Dellinger Open. ¶¶55). Dr. Dellinger thus has proper grounds to opine on the technical aspects of noninfringing alternatives and whether or not that science drives sales. Any issues Grace has with the testimony can be addressed during cross-examination. *Daubert*, 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking [] evidence.")

After reviewing the parties's briefing, it is also evident that cross-examination is also an appropriate means to address Grace's concerns regarding testimony on actions in obtaining noninfringing alternatives and the costs associated. For these reasons, the Court denies Grace's *Daubert* motion, D.I. 210.

f. Dr. Aeri Park

Elysium seeks to exclude Dr. Aeri Park's opinions "that assume infringement." D.I. 189 at 4. Elysium asserts that "Dr. Park considered tests from a small percentage of NR-Cl batches and presumes they are 'representative' of all batches without justification." D.I. 261 at 18.

"[A]n expert's testimony is admissible so long as the process or technique the expert used in formulating the opinion is reliable." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 744 (3rd Cir. 1994). "The [Rule 702] inquiry is a flexible one . . . [and its focus] must be solely on principles and methodology, not on the conclusions that they generate." *Daubert*, 509 U.S. at 595. "'[T]he reliability analysis [required by *Daubert*] applies to all aspects of an expert's testimony: the methodology, the facts underlying the expert's opinion, [and] the link between the facts and the

conclusion.'" *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 291 (3d Cir. 2012) (quoting *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 155 (3d Cir. 1999)); *see also* FED. R. EVID. 702. "'A court may conclude that there is simply too great a gap between the data and the opinion proffered.'" *Magnetar Techs. Corp. v. Six Flags Theme Parks Inc.*, C.A. No. 07-127-LPS-MPT, 2014 WL 529983, at *4 (D. Del. Feb. 7, 2014) (citations omitted).

One of Elysium's primary concerns regarding Dr. Park's testimony relies on a "small percentage" of batches and "presumes they are 'representative' of all batches." D.I. 261 at 18. These arguments go to the weight, not the admissibility, of the evidence. *VLSI Technology LLC v. Intel Corporation*, C.A. 18-966-CFC-CJB, 2022 WL 2304112, at *4 (D. Del. June 27, 2022) (denying motion to strike expert opinion that relied on a single simulation to support that all versions of the accused products infringed). Therefore, Elysium's motion as to Dr. Aeri Park's opinions is denied.

g. Kimberly Schenk

Elysium filed two *Daubert* motions to preclude the testimony of Grace's damages expert Kimberly Schenk. D.I. 187; D.I. 188. The first motion seeks to preclude Ms. Schenk's opinions that rely on Dr. Park's testimony, addressed above *supra* §II.B.f. Because this Court determined that Dr. Park's testimony is admissible, the Court will not preclude Ms. Schenk's testimony on these grounds. *EMC Corp. v. Pure Storage, Inc.*, 154 F. Supp. 3d 81, 115 (D. Del. 2016) ("It is perfectly reasonable for a finance and damages expert to adopt the conclusions of other experts. Whether those conclusions are sound can be explored at trial through cross examination and other expert testimony.") Thus, this Court will turn to the arguments of apportionment of batches and apportionment among Asserted Patents.

Elysium asserts that "even if Dr. Park is permitted to offer testimony on the batches she analyzed, [Ms.] Schenk's damages opinions still must be excluded because she does not provide any opinion or methodology for the jury to determine what damages Elysium might owe Grace for any subset of batches." D.I. 261 at 23. To allow such testimony, Elysium asserts, would be to shift the burden to Elysium to show that all products are like the one tested. D.I. 189 at 8.

During the provisional rights period, Elysium obtained its NRCl from PCI and AMPAC. Dr. Park analyzed PXRD patterns of NRCl from PCI and AMPAC and concluded that all samples contained Form I, Form II, or a mixture thereof. D.I. 227 at 8 (citing Ex. 2 (Park Reply Rpt.) ¶¶ 37-38, 40, 47). Ms. Schenk's analysis does provide a means to adjust her provisional rights damages by reducing the royalty base, but maintaining the royalty rate because "the parties to the hypothetical negotiation would have negotiated a royalty rate that is not conditional on the form of NRCl produced, similar to [redacted]" D.I. 228, Ex. 7 (Schenk Reply Rpt.) ¶114. Ms. Schenk's analysis is acceptable, as Federal Circuit's precedent allows apportionment to be addressed in a variety of different ways, including "by careful selection of the royalty base to reflect the value added by the patented feature, where that differentiation is possible; by adjustment of the royalty rate so as to discount the value of a product's non-patented features; or by a combination thereof." *Ericsson, Inc. v. D-Link Sys.*, Inc., 773 F.3d 1201, 1226 (Fed. Cir. 2014).

Elysium also asserts that "Ms. Schenk's damages opinions also are flawed because they do not apportion between the patents." D.I. 189 at 9. Grace disagrees, first by asserting that Ms. Schenk does apportion by patent and second, by arguing that Ms. Schenk's methodology relies on a comparable license agreement, [redacted] and thus does not need to apportion by patent. D.I. 227 at 14.

First, Ms. Schenk's analysis concludes that "both lost profits and reasonable royalty damages for this period [following the filing of the Complaint] should be attributed 100% to the Form I Patents" during the period of time following the complaint. D.I. 228, Ex. 7, (Schenk Reply Rpt.) ¶113 (relying on Dr. Park's reports). She next explains that her analysis would not change dependent if one Form I patent was found invalid, not infringed, or unenforceable because the "lost tested contained Form I NRCl" as claimed in both patents. *Id.*

"When a sufficiently comparable license is used as the basis for determining the appropriate royalty, further apportionment may not necessarily be required." *Vectura Ltd. v. GlaxoSmithKline LLC*, 981 F.3d 1030, 1040 (Fed. Cir. 2020). "That is because a damages theory that is dependent on a comparable license. . . may in some cases have 'built-in apportionment.'" *Id.* "Built-in apportionment effectively assumes that the negotiators of a comparable license settled on a royalty rate and royalty base combination embodying the value of the asserted patent." *Id.* at 1041. It is not uncommon to provide royalty rates that subsume multiple asserted patents. *See, e.g., Bio-RadLabs.*, 967 F.3d at 1372-73; *VirnetX, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308, 1330 (Fed. Cir. 2014). Elysium's arguments showing how the [redacted] license should be considered in a hypothetical negotiations analysis, *see* D.I. 261 at 24 (citing to Elysium's own expert analysis on the differences), go to the weight of the testimony and not the admissibility. *Daubert*, 509 U.S. at 596.

III. SUMMARY JUDGMENT MOTIONS

Pending before the Court are Grace's Motions for Summary Judgment, D.I. 191, D.I. 192, D.I. 193, D.I. 194, and Elysium's Motions for Summary Judgment, D.I. 197, D.I. 198, D.I. 199, D.I. 200. The below analyses are made in light of the Court's ruling on the parties' *Daubert* motions above.

A. Legal Standards

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a). Material facts are those "that could affect the outcome" of the proceeding. *Lamont v. New Jersey*, 637 F.3d 177, 181 (3d Cir. 2011) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). "[A] dispute about a material fact is 'genuine' if the evidence is sufficient to permit a reasonable jury to return a verdict for the nonmoving party." *Id.* (citations omitted). "The burden on the moving party may be discharged by pointing out to the district court that there is an absence of evidence supporting the non-moving party's case." *Peloton Interactive, Inc. v. iFIT Inc.*, C.A. No. 20-1535-RGA, 2022 WL 1523112, at *1 (D. Del. May 13, 2022) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986)).

The burden then shifts to the non-movant to demonstrate the existence of a genuine issue for trial. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87 (1986); *Williams v. Borough of West Chester*, 891 F.2d 458, 460-61 (3d Cir. 1989). A non-moving party asserting that a fact is genuinely disputed must support such an assertion by: "(A) citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations . . . , admissions, interrogatory answers, or other materials; or (B) showing that the materials cited [by the opposing party] do not establish the absence . . . of a genuine dispute . . . ." FED. R. CIV. P. 56(c)(1).

When determining whether a genuine issue of material fact exists, the court must view the evidence in the light most favorable to the non-moving party and draw all reasonable inferences in that party's favor. *Wishkin v. Potter*, 476 F.3d 180, 184 (3d Cir. 2007). If the non-moving party fails to make a sufficient showing on an essential element of its case with respect to which it has

the burden of proof, the moving party is entitled to judgment as a matter of law. *See Celotex Corp.*, 477 U.S. at 322.

B. Discussion[3]

a. Inequitable Conduct

"The inquiry is whether, viewing the evidence in the light most favorable to [Elysium], no reasonable trier of fact could find the [patentees] acted with the specific intent to deceive the PTO." *Sysmex Corp. v. Beckman Coulter, Inc.*, No. CV 19-1642-JFB-CJB, 2022 WL 1503987, at *4 (D. Del. May 6, 2022), report and recommendation adopted, C.A. No. 19-1642-JFB-CJB, 2022 WL 1744573 (D. Del. May 31, 2022) (quoting *Alcon Rsch., Ltd. v. Apotex, Inc.*, C.A. No. 1:09-102-RLY-TAB, 2013 WL 2244338, at *8 (S.D. Ind. May 21, 2013). "Put another way, summary judgment of no inequitable conduct should be denied if, drawing all reasonable inferences in favor of [Elysium], a reasonable factfinder could reasonably find that intent to deceive is the single most reasonable inference." *Id.* (citing *Sprint Commc'ns Co. LP v. Charter Commc'ns, Inc.*, C.A. No. 17-1734-RGA, 2021 WL 982728, at *4-5 (D. Del. Mar. 16, 2021); *CliniComp Int'l, Inc. v. Athenahealth, Inc.*, C.A. No. 18-00425-LY, 2020 WL 7011769, at *5 (W.D. Tex. Nov. 10, 2020); *Helios Software, LLC v. Awareness Techs., Inc.*, C.A. No. 11-1259-LPS, 2015 WL 12806482, at *13 (D. Del. Apr. 13, 2015)).

[3] The Court ordered the parties to rank the grounds for summary judgment raised in their motions with the understanding that "[i]f the Court decides to deny a motion filed by the party, barring exceptional reasons determined *sua sponte* by the Court, the Court will not review any lower ranked summary judgment motions filed by the party." D.I. 183. Grace ranked "No Summary Judgment of No Inequitable Conduct" first. D.I. 191. Elysium ranked "Summary Judgment that U.S. Patent Nos. 10,323,058, and 10,233,207 are Invalid Under 35 U.S.C. § 102(a) for Violating the on Sale Bar" first. D.I. 197.

In the Court's view, Grace's motion should be denied. In denying the motion to dismiss the inequitable conduct claims, the Court found that:

> Read in the light most favorable to Elysium, the Court may reasonably infer that Carlson knew of his duty to disclose information to the PTO, knew of the crystalline NRCl that practiced the Asserted Patents in 2013, and intentionally failed to disclose its existence. The Court may also reasonably infer that Reynolds was involved in patent prosecution, determined in September 2018 that Grace had not yet disclosed the crystalline NRCl sales to the PTO, and intentionally avoided such disclosure.

D.I. 225 at 9.

Intent and materiality are separate requirements for determining inequitable conduct. *Hoffmann–La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1359 (Fed.Cir.2003). With respect to materiality of the sales, genuine issues of material fact exist, detailed below, § IV.B.b. Now, at the summary judgment stage, the Court searches for the facts that can lead to the reasonable inference that Mr. Carlson and Mr. Reynolds intentionally deceived the USPTO. "A district court may infer intent from indirect and circumstantial evidence," *Therasense*, 649 F.3d at 1290. Elysium alleges facts that suggest intent. For example, Elysium points to the following instances in its concise statement of acts:

- Mr. Carlson and Mr. Reynolds being aware that Grace was planning to produce a white crystalline powder, D.I. 233 ¶ 1,
- Mr. Carlson signing batch records "that identify pre-priority date crystalline NRCL" that was sold to a third party, *id.* ¶ 16, neither Mr. Carlson nor Mr. Reynolds performed or sought to perform XRPD testing while applications were pending, *id.* ¶ 3,[4]

[4] Elysium's Counterstatement of Facts, D.I. 233, often cites to deposition testimony of a Mr. Short, who is not a named defendant in the inequitable conduct claims pending before the Court. *See* D.I. 225. Elysium asks this Court to infer that Mr. Short, not a named defendant, having conversations with legal counsel implies inequitable conduct. First, Elysium failed to make a

- Mr. Reynolds requesting another Grace employee to compile purchase order numbers and shipment dates for customer ChromaDex, *id.* ¶ 5, and
- Mr. Reynolds and Mr. Carlson are aware of a duty to disclose material information before the USPTO, *id.* ¶¶ 17-18.

In the Order granting-in-part the motion to dismiss, the Court noted that:

> Elysium's allegations also support a finding that Reynolds's intent to deceive the PTO is the single most reasonable inference. Grace alleges that "[t]he only possible conclusion" is that Reynolds's order to Smith not to further research the 2013 batch orders was "because of Grace's desire to mislead the US PTO . . . ." D.I. 113 ¶ 70; *see also* D.I. 113 ¶ 76 (making similar allegations as to Grace as a whole, but not as to individuals). No alternative inference is alleged.

D.I. 225 at 10 n.3.

At this summary judgment stage, Elysium again raises the alleged research project. D.I. 229 at 6. ("Mr. Reynolds asked his admin. Ms. Peggy Smith also to compile a [] research project, but Mr. Reynolds inexplicably stopped that work only three hours later. At deposition, Mr. Reynolds testified that he had no recollection of this research project." (citations and quotations omitted)). Still, there does not appear to be an alternative inference. *See* D.I. 229 at 6.

Elysium also cites to deposition transcripts to show that Mr. Reynolds and Mr. Carlson were involved in patent prosecution and were aware of their duty to disclose. D.I. 229 at 10-11.

Thus, Elysium has sufficiently shown that there is a genuine issue of material fact as to whether Reynolds and Carlson knew of sales of the invention (which is disputed, *see* § IV.B.b) a

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showing of specific intent against Mr. Short at the motion to dismiss stage, D.I. 225, and "no adverse inference shall arise from invocation of the attorney-client and/or work product privilege." *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337, 1344 (Fed. Cir. 2004)).

year before the applications for the Form I patents were filed, knew of the on-sale bar imposed by 35 U.S.C. § 102, and intentionally withheld information of the sales from the USPTO. *See Lear Corp. v. NHK Seating of Am. Inc.*, No. 13-12937, 2022 WL 876021, at *11 (E.D. Mich. Mar. 23, 2022) ("Adapting [*Therasense*'s] prior-art test to the on-sale-bar context, the [defendant] must prove by clear and convincing evidence that someone involved in the prosecution of the [Accused Patents] knew" that the alleged offers for sale were material and thus knew that the patent office would reject the patent application if it were informed of the offers for sale).

Because there is genuine issue of fact as to whether Mr. Reynolds and Mr. Carlson had the intent to deceive the USPTO, this Court denies Grace's Motion for Summary Judgment of No Inequitable Conduct, D.I. 191.

b. On-Sale Bar

For the reasons discussed below, Elysium's Summary Judgment Motion, D.I. 197, is denied. Elysium moves for summary judgment regarding the validity of the Form I patents in light of the on-sale bar codified in 35 U.S.C. § 102. The Court denies Elysium's motion, finding genuine issues of material fact ripe for a fact-finder.

The "on-sale bar applies when two conditions are satisfied before the critical date." *Pfaff v. Wells Elecs.*, Inc., 525 U.S. 55, 67 (1998) (citing 35 U.S.C. § 102(b)). "First, the product must be the subject of a commercial offer for sale," and "[s]econd, the invention must be ready for patenting." *Id.* "That condition may be satisfied in at least two ways: by proof of reduction to practice before the critical date; or by proof that prior to the critical date the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention." *Id.* at 67-68.

In this case, the three Asserted Patents each claim one of two crystalline forms of NRCl, Form I and Form II. The Court has construed the word "Form" for these patents to mean "can be identified by one or more of the analytical methods described in the specification." D.I. 109. Elysium asserts that the Form I patents, which have a critical date of July 24, 2013, are invalidated by the on-sale bar because an allegedly commercial batch, Batch 13101, was manufactured by Grace in early 2013 in Albany, Oregon. D.I. 202 at 6-7. Elysium asserts that Grace provided samples of Batch 13101 to customer ChromaDex, and "after review and testing ChromaDex issued a Purchase Order on May 1, 2013 to buy [redacted]." *Id.* at 7. The Purchase Order is excerpted below:

Vendor:	Ship To:
W.R. Grace & Co. - Conn. (Synthetech, Inc.) 7500 Grace Drive Columbia, MD 21044 Fax: 541-967-9424	Chromadex, Inc. 10005 Muirlands Blvd Suite G Irvine, CA 92618

Vendor Item #	Description	Req Date	QTY	Unit Price	Extended Price
VEN#-00014315-000	NICOTINAMIDE RIBOSIDE CHLORIDE(DS) 1kg	5/1/2013	[redacted]	[redacted]	[redacted]
Quality per agreement with ChromaDex.					

D.I. 205, Ex. 25.

Grace asserts that there is a genuine issue of material fact here: that the parties disagree as to whether Batch 13101 was Form 1. D.I. 231 at 5. Grace provides multiple disputed facts in support of its request to the Court to deny this motion. First, Grace does not agree with Elysium that Form I and Form II are the only two forms of NRCl. *Id.* at 5-6. ("Elysium's own experts agree that at least one form disclosed by GSK is not Form I or II, and they also cited a Chinese patent that purportedly describes another form."). Second, Grace points to Dr. Rogers' testimony wherein Dr. Rogers proffers that the PXRD analysis of Batch 13101's retainer sample does not show definitively that Batch 13101 is Form I and, in fact "there are significant differences" and

"indicate that the two diffraction patterns do not represent the same solid-state form." D.I. 236, Ex. 1 (Rogers Rpt.) ¶ 189. Dr. Rogers also notes that Batch 13101 and Batch 13202 (a confirmed Form 1 NRCl) have differences in terms of water content and melting point, suggesting that Batch 13101 may be amorphous. D.I. 231 at 8 (citing D.I. 236, Ex. 1 (Rogers Rpt.) ¶ 199-206.

Grace also contends that, while Elysium asserts that "the patents' table of IR values for Form I align with the IR values from Batch 13101," the experts in this case agree that "a POSA would understand that IR cannot always be used to distinguish between crystalline forms." D.I. at 10 (citing D.I. 236, Ex. 1, (Rogers Rpt.) ¶¶364; Ex. 2, (Park Opening Rpt.) ¶¶55-56; Ex. 3, (Steed Tr.) 105:21-106:6; Ex. 6, (Perni Tr.) 220:5-13). Furthermore, there are factual disputes regarding whether the IR peak list in the Form I patents came from Batch 13101, D.I. 231 at 12, and whether the process used to make Batch 13101 necessarily makes Form I each time. D.I. 231 at 13. For all these reasons, the Court finds that there exists a genuine issue of material dispute regarding Batch 13101 being Form I and declines to grant Elysium's summary judgment on those grounds.

Elysium also raises an argument regarding Batch 13201, undisputed to be Form I, was offered for sale prior to the critical date. A copy of a purchase order, dated May 29, 2013, is excerpted below:

Vendor:

W.R. Grace & Co. - Conn. (Synthetech, Inc.)
7500 Grace Drive
Columbia MD 21044

Ship To:

*Address listed with item below.

Contract Number:

Shipping Method	Payment Terms		Confirm With		Page
	Net 30				1
L/N Item Number	Description	Req. Date	U/M	Ordered	Unit Price	Ext. Price
Project Number	Cost Category ID	Billing Note				
Shipping Method	Reference Number	FOB				
1 VEN#-00014315-000		5/29/2013	[redacted]			
	VEN#-00014315-000	None				
Per ChromaDex product specifications.						
Deliver To:						

D.I. 236, Ex. 33.

While the purchase order above does not contain the chemical name, Grace provides the following chart showing that Batch 13201 was subject to a May 29, 2013 purchase order with a manufacturing start date on July 25, 2013:

Batch	Purchase Order Date	Manufacturing Start	Manufacturing Complete	Delivery
13101	May 1, 2013	April 15, 2013	April 27, 2013	May 24, 2013
13201	May 29, 2013	July 25, 2013	Aug. 18, 2013	Sept. 4, 2013

D.I. 231 at 3.

Thus, Batch 13201 appears to be the subject of a commercial offer for sale prior to July 24, 2013. Notably, however, the purchase order above does not request Form I specifically and does not include the requested chemical name. Thus, a genuine issue of material fact exists as to whether the offer for sale of Batch 13201 was an offer for sale of Form I. While it is known now that Batch 13201 is Form I, the manufacturing process may not have begun until after the critical date. *Sparton Corp. v. U.S.*, 399 F.3d 1321, 1325 (Fed. Cir. 2005) (finding there was not an offer for sale of the patented device where the release plates were ultimately included in the delivery, but not reflected in the offer); *Tec Air, Inc. v. Denso Mfg. Michigan Inc.*, 192 F.3d 1353, 1358 (Fed. Cir. 1999) ("the jury reasonably could have found that Tec Air's offers to []did not raise the on-sale bar because the subject matter of these offers does not fully anticipate the claimed invention."). The law requires that the invention must have been ready for patenting. *Pfaff*, 525 U.S. at 67.

In sum, the parties dispute (1) whether Batch 13101 is Form I, and (2) whether Form I was ready for patenting at the time Batch 13201 was offered for sale. Thus, genuine issues of material

fact exist and Elysium's motion for summary judgment as to invalidity of the Form I patents under 35 U.S.C. § 102 is denied.

IV. CONCLUSION

For the foregoing reasons, the Court grants-in-part Plaintiff's Motion to exclude the testimony of Robert Armitage (D.I. 206), grants-in-part Plaintiff's motion to exclude testimony of Dr. Robert Perni and Dr. Robert Steed (D.I. 207), denies Plaintiff's Motion to exclude the entire testimony of Dr. Perni (D.I. 208), denies Plaintiff's Motion to exclude the testimony of Alexander Clemons (D.I. 209), denies Plaintiff's motion to preclude the testimony of Dr. Ryan Dellinger (D.I. 210), denies Defendant's motion to preclude testimony of Dr. Aeri Park (D.I. 186), denies both of Defendant's motions to preclude the testimony of Kimberly Schenk regarding damages, (D.I. 187; D.I. 188), denies Grace's motion for summary judgment of no inequitable conduct, (D.I. 191), denies Grace's motions for summary judgment (D.I. 192, D.I. 193, D.I. 194), denies Elysium's motion for summary judgment of invalidity under 35 U.S.C. § 102 (D.I. 197) and denies Elysium's remaining motions for summary judgment (D.I. 198, D.I. 199, D.I. 200).

***

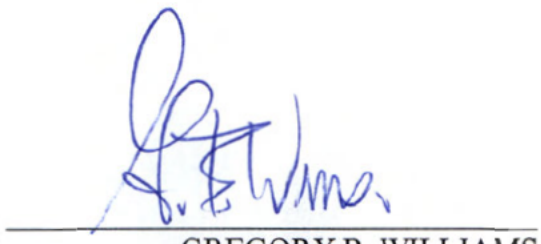
WHEREFORE, on this 3rd day of August, 2023, IT IS HEREBY ORDERED that:

1. Grace's *Daubert* Motion to Exclude the Testimony of Robert Armitage (D.I. 206) is **GRANTED-IN-PART, DENIED-IN-PART**.
2. Grace's *Daubert* Motion to Exclude Testimony of Dr. Robert Peri and Dr. Robert Steed, in part (D.I. 207) is **GRANTED-IN-PART**, **DENIED-IN-PART**. Drs. Perni and Steed are precluded from offering testimony and opinions expressed in Dr. Perni's Opening Report at paragraphs 186-187, 190-193, and 221-263, and in Dr. Steed's Opening Report

at paragraphs 173-174, 177-180, and 203-243 that opine on Grace's knowledge, intent, motivation, or state of mind.

3. Grace's *Daubert* Motion to Exclude Testimony of Dr. Perni in its Entirety (D.I. 208) is **DENIED**.
4. Grace's *Daubert* Motion to Exclude the Testimony of Alexander Clemons, in part, (D.I. 209) is **DENIED.**
5. Grace's *Daubert* Motion to Exclude the Testimony of Dr. Ryan Dellinger, in part, (D.I. 210) is **DENIED.**
6. Elysium's *Daubert* Motion to Exclude the Expert Testimony of Dr. Aeri Park (D.I. 186) is **DENIED**.
7. Elysium's *Daubert* Motions to Exclude the Expert Testimony of Ms. Kimberly Schenk (D.I. 187; D.I. 188) are **DENIED**.
8. Grace's Motion for Summary Judgment of No Inequitable Conduct (D.I. 191) is **DENIED**.
9. Grace's remaining Motions for Summary Judgment (D.I. 192; D.I. 193; D.I. 194) are **DENIED**.
10. Elysium's Motion for Summary Judgment that U.S. Patent Nos. 10,323,058 and 10,233,207 are Invalid Under 35 U.S.C. § 102(a) for Violating the on Sale Bar (D.I. 197) is **DENIED**.
11. Elysium's remaining Motions for Summary Judgment (D.I. 197, D.I. 198, D.I. 199, D.I. 200) are **DENIED**.
12. Because this Memorandum Order is filed under seal, the parties shall meet and confer and submit a joint proposed redacted version no later than seven (7) days after the date of this

Memorandum Order. In the absence of a timely request compliant with applicable standards, the Court will unseal the entire Memorandum Order.



GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE

CERTIFICATE OF SERVICE

I, Daniel A. O'Brien, hereby certify that on this 10th day of August, 2023, a copy of the foregoing document was electronically filed with the court and served via CM/ECF, on parties with counsel of record identified on the Court's docket.

/s/ Daniel A. O'Brien
Daniel A. O'Brien (No. 4897)

EXHIBIT 59

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PERSAWVERE, INC., Plaintiff, v. MILWAUKEE ELECTRIC TOOL CORPORATION, Defendant.	C.A. No. 21-400-GBW

PLAINTIFF PERSAWVERE, INC.'S OPENING BRIEF IN SUPPORT OF ITS *DAUBERT* MOTION TO EXCLUDE EXPERT TESTIMONY OF GREGORY GONSALVES, PH.D.

Dated: July 21, 2023

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I. INTRODUCTION

Defendant Milwaukee Electric Tool Corporation's ("Milwaukee") expert, Dr. Gregory Gonsalves, offered multiple improper opinions. Not only did he opine on the law surrounding patent prosecution and inequitable conduct, but he offered opinions regarding the intent of Scott McIntosh, the inventor of the patent-in-suit, to commit inequitable conduct. Such testimony has been repeatedly rejected by this Court as outside the proper purview of expert testimony. Plaintiff Persawvere, therefore, respectfully submits this opening brief in support of its motion to exclude the opinions of Dr. Gregory Gonsalves under *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993) and Fed. R. Evid. 702.

II. NATURE AND STAGE OF THE PROCEEDINGS

Plaintiff Persawvere, Inc. ("Persawvere") initiated this litigation on March 19, 2021, alleging that Milwaukee infringes various claims of the U.S. Patent No. 8,607,681 ("the '681 patent") entitled "Hand-Held Band Saw." *See* D.I. 1. Fact and expert discovery are closed. Trial is set to begin December 4, 2023. D.I. 72.

III. SUMMARY OF THE ARGUMENT

The Court should exclude Dr. Gonsalves' improper testimony.

1. Dr. Gonsalves should not be permitted to offer legal opinions regarding the governing law, including on the issues of inequitable conduct and the duty of candor. *See, e.g., Berckeley Inv. Grp., Ltd. v. Colkitt*, 455 F.3d 195, 217 (3d Cir. 2006) ("[T]he District Court must ensure that an expert does not testify as to the governing law of the case" or "render[] a legal opinion . . . as it would usurp the District Court's pivotal role in explaining the law to the jury") (internal citations omitted); *see also PureWick Corp. v. Sage Prod., LLC*, No. CV 19-1508 (MN), 2021 WL 2593338, at *2, n.3 (D. Del. June 24, 2021) ("[I]n this district . . . we have a very consistent view . . . that [testimony of patent law experts] are not helpful. And not only do we

mostly exclude them on bench trials, but in jury trials they are so severely limited." Such "testimony is unhelpful and inappropriate in that it substitutes the judgment of the expert for that of the Court.").

2. Dr. Gonsalves should not be permitted to offer opinions regarding any subjective issues, including with regard to intent, motive, or state of mind (or evidence by which such state of mind may be inferred) to deceive the Patent Office. *See, e.g.*, *Greatbatch Ltd. v. AVX Corp*., No. CV 13-723-LPS, 2017 WL 3176179, at *2 (D. Del. July 20, 2017), *aff'd*, 813 F. App'x 609 (Fed. Cir. 2020) (striking expert opinions as to the state of mind and intent as "improper legal conclusions based on unscientific interpretation").

IV. STATEMENT OF FACTS

Milwaukee retained a purported expert on the subject of patent law, Dr. Gonsalves, an attorney, to render opinions regarding (1) United States patent practice and procedures generally, and specifically as they relate to the prosecution of patent application that resulted in the issuance of the asserted '681 patent, and (2) the inequitable conduct defense advanced at the close of fact discovery by Milwaukee. Dr. Gonsalves submitted his opening expert report on May 8, 2023. Ex. A (Gonsalves Op. Rpt.). On June 26, 2023, Dr. Gonsalves submitted his reply expert report. Ex. B (Gonsalves Reply Rpt.).

The opening report of Dr. Gonsalves includes an overview of the U.S. patent system and patent prosecution procedures before the U.S. Patent and Trademark Office ("PTO"), including a discussion of related legal requirements and precedents. *See* Ex. A (Gonsalves Op. Rpt.) ¶¶ 28-81. It also includes an overview of the asserted '681 patent and selected issues and interpretations of its prosecution history. *Id*. ¶¶ 82-102. The bulk of Dr. Gonsalves's reports concerns the topic of inequitable conduct and the duty of candor, which he opines were breached by the sole inventor of

the '681 patent, Mr. Scott McIntosh. *Id.* ¶¶ 103-149; *see also* Ex. B (Gonsalves Reply Rpt.) ¶¶ 116-178.

Dr. Gonsalves's inequitable conduct discussion includes a detailed account of purportedly "relevant case law" as well as discussions of his interpretations of the "current state of the law," including cases in which the Federal Circuit affirmed findings of inequitable conduct. Ex. A (Gonsalves Op. Rpt.) ¶¶ 103-125.

Dr. Gonsalves further opines on Mr. McIntosh's alleged failure to satisfy the duty of candor to disclose information material to patentability, including his opinions regarding Mr. McIntosh's subjective "intent to deceive the PTO in order to obtain [the] patent." Ex. A (Gonsalves Op. Rpt.) ¶¶ 126-149; Ex. B (Gonsalves Reply Rpt.) ¶¶ 138-178.

V. ARGUMENT

Rule 702 governs the admissibility of qualified expert testimony and only allows expert opinion testimony if it is based on "scientific, technical, or other specialized knowledge" by a qualified expert and if it "will help the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702. "Rule 702 embodies three distinct substantive restrictions on the admission of expert testimony: qualifications, reliability, and fit." *Elcock v. Kmart Corp.*, 233 F.3d 734, 741 (3d Cir. 2000).

The Supreme Court has assigned "to the trial judge the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993). The proffering party has the burden to establish by a preponderance of the evidence that the testimony is reliable. *Id.* at 592, n.10. To be reliable, "the expert's opinion must be based on the methods and procedures of science rather than on subjective belief or unsupported speculation" and "the expert must have good grounds for his or her belief."

Calhoun v. Yamaha Motor Corp., U.S.A., 350 F.3d 316, 321 (3d Cir. 2003) (internal quotation marks and citation omitted).

The *Daubert* principles apply in a bench trial in generally the same manner as in a jury trial. *Chase Manhattan Mortg. Corp. v. Advanta Corp.*, No. CIV.A. 01-507 (KAJ), 2004 WL 422681, at *9 (D. Del. Mar. 4, 2004); *PureWick Corp. v. Sage Prod., LLC*, No. CV 19-1508 (MN), 2021 WL 2593338, at *2, n.3 (D. Del. June 24, 2021) ("[I]n this district . . . we have a very consistent view . . . that [testimony of patent law experts] are not helpful. And not only do we mostly exclude them on bench trials, but in jury trials they are so severely limited." Such "testimony is unhelpful and inappropriate in that it substitutes the judgment of the expert for that of the Court.").

VI. OPINIONS OF DR. GONSALVES ON PATENT LAW AND INEQUITABLE CONDUCT SHOULD BE EXCLUDED

1. Dr. Gonsalves' Testimony Regarding Patent Law, Including Inequitable Conduct, Is An Improper Attempt to Instruct the Court on the Law and Offer Impermissible Legal Opinions

Although Dr. Gonsalves classifies his opinions as concerning "United States patent practice and procedures," generally, and specifically with respect to the '681 patent (*see* Ex. A (Gonsalves Op. Rpt.) ¶ 1), his reports center on his legal opinions regarding caselaw, as well as legal analysis and legal conclusions on substantive issues of the case. Such opinions would be wholly impermissible if offered to a jury. While Milwaukee has recognized that the issue of inequitable conduct is tried to the Court, not the jury,[1] such opinions have zero probative value in a bench trial.

Courts in this District "ha[ve] a well-established practice of excluding the testimony of legal experts, absent extraordinary circumstances." *AstraZeneca UK Ltd. v. Watson Lab'ys, Inc. (NV)*, No. CA 10-915-LPS, 2012 WL 6043266, at *1 (D. Del. Nov. 14, 2012) (excluding patent law

[1] Milwaukee confirmed that "they do not anticipate Dr. Gonsalves testifying in front of the jury but do reserve [their] right to have him testify before the court for any bench trial addressing Milwaukee's inequitable conduct claim." *See* Ex. C.

expert testimony, including on procedures at the PTO) (internal citations omitted); *Berckeley Inv. Grp., Ltd. v. Colkitt*, 455 F.3d 195, 217 (3d Cir. 2006) ("The District Court has discretion to determine whether expert testimony will help the trier of fact . . . In utilizing that discretion, however, the District Court must ensure that an expert does not testify as to the governing law of the case.") (internal citations omitted). Particularly, "[t]he law of this district is clear that experts in patent cases may not opine on whether a party engaged in inequitable conduct, discuss whether certain information was material to a pending patent application, or otherwise provide legal conclusions on 'substantive issues of patent law.'" *Brigham & Women's Hosp. Inc. v. Teva Pharms. USA, Inc*., No. CIV.A. 08-464, 2010 WL 3907490, at *2 (D. Del. Sept. 21, 2010) (citing cases); *Shire Viropharma Inc. v. CSL Behring LLC*, No. CV 17-414, 2021 WL 1227097, at *16 (D. Del. Mar. 31, 2021) (excluding patent law expert testimony regarding legal requirements and legal conclusions on the inequitable conduct). "Similarly, in this district parties are generally not permitted to explain patent prosecution histories through expert testimony." *Brigham & Women's Hosp.*, 2010 WL 3907490, at *2. Indeed, "descriptions of the law and instructions on the law are matters for the court" and any "such testimony frequently amounts to the proffering of impermissible legal opinions." *AstraZeneca*, 2012 WL 6043266, at *1 (citations omitted); *Shire Viropharma*, 2021 WL 1227097, at *16 (excluding patent law expert testimony regarding legal requirements and conclusions on the duty of candor and inequitable conduct as improper legal opinions); *see also Lannett Co. Inc. v. KV Pharm., Drugtech Corp*., No. CV 08-338-JJF, 2009 WL 10657988, at *4 (D. Del. Mar. 9, 2009) (excluding legal expert opinions as an improper attempt "to offer testimony on the ultimate legal issue in the case"—patent unenforceability due to alleged inequitable conduct—"usurping the role of the trial judge"); *see also PureWick Corp.,* 2021 WL 2593338, at *2, n.3 (noting that this Court traditionally excludes patent law expert testimony

regarding legal issues tried to the bench such as inequitable conduct). Dr. Gonsalves' expert reports include all such impermissible testimony.

The opening report of Dr. Gonsalves demonstrates that Milwaukee intends to offer him as an expert on the legal standards and case law, as well as legal opinions, including summaries and interpretations of: (a) the U.S. laws and regulations generally relating to patents and patent prosecution (Ex. A ¶¶ 28-32); (b) legal requirements for patent applications and parts thereof, including the legal standard for written description and enablement (Ex. A ¶¶ 33-43); (c) legal requirements for filing and prosecuting a patent application (Ex. A ¶¶ 44-48); (d) legal requirements for claiming the benefit of the filing date of an earlier filed application (Ex. A ¶¶ 49-53); (e) "the rules and procedures that govern patent application examination" and a legal opinion that the "USPTO procedures for examination of patent application were not followed" (Ex. A ¶¶ 54-56); (f) legal requirements imposed on applicants and patent examiners during patent prosecution (Ex. A ¶¶ 57-75); (g) legal requirements relating to the duty of candor and good faith, and duty of disclosure (Ex. A ¶¶ 76-81); and expert explanation and interpretation of the '681 patent and its prosecution history (Ex. A ¶¶ 82-102). These sections are infused with citations to statutes, regulations, and legal precedent, as well as Dr. Gonsalves's opinions on the law, beyond mere overview of "internal PTO practices and procedures." *Shire Viropharma*, 2021 WL 1227097, at *16 (excluding improper legal analysis and opinions by a patent law expert despite his suggestion that his testimony is simply about "internal PTO practices and procedures," which rarely may be allowed if no impermissible legal opinions are offered or otherwise the expert does not usurp the function of the Court) (citing cases). In short, paragraphs 28-102 of Dr. Gonsalves' opening report demonstrate an improper attempt to instruct the Court on the applicable law, and to offer legal conclusions. These sections of Dr. Gonsalves' report should be excluded. *See, e.g.*, *AstraZeneca UK*, 2012 WL 6043266, at *2

(excluding legal expert report, including on procedures at the PTO, as "not . . . helpful to the Court.").

The opening and reply reports of Dr. Gonsalves further demonstrate that Milwaukee intends that he offer opinions, legal analysis, and conclusions, concerning the alleged inequitable conduct and the duty of candor. Ex. A (Gonsalves Op. Rpt.) ¶¶ 103-149; Ex. B (Gonsalves Reply Rpt.) ¶¶ 138-178. Dr. Gonsalves offers his opinions regarding his legal analysis of what he considers to be the "relevant case law" and with regard to his "understanding of the current state of the law," including his legal analysis of caselaw concerning inequitable conduct, the duty of candor, and the duty of disclosure of information material to patentability imposed on patent practitioners and inventors. Ex. A ¶¶ 103-125. He further opines on the alleged inequitable conduct and breach of duty of candor before the Patent Office, including: (a) legal opinions on allegedly material misconduct due to filing allegedly false declaration by Mr. McIntosh (Ex. A ¶¶ 126-133; Ex. B ¶¶ 138-148 appearing on pages 4-7[2]); (b) legal analysis and conclusions regarding an alleged failure to show reasonable inference from purported failure to disclose material prior art information other than an intent to deceive (Ex. A ¶¶ 134-135, 146-148; Ex. B ¶¶ 145-147 appearing on pages 7-8, ¶¶ 164-166 appearing on pages 15-16); (c) legal opinions regarding prior art materiality (Ex. A ¶¶ 136-145; Ex. B ¶¶ 148-163 appearing on pages 8-15); and (d) legal opinions and characterizations regarding prior art, including if it was non-cumulative to other considered information (Ex. B ¶¶ 167-177).

[2] The numbering of paragraphs in of Dr. Gonsalves' reply expert report is incorrect and misplaced. On page 4, paragraph "11" follows by paragraph "116" and then by paragraph "138." On page 7, after paragraph "148," there is paragraph "145." To avoid any confusion, the references are provided to both page and paragraph numbers, where applicable.

All of this is impermissible. "[E]xperts in patent cases may not opine on whether a party engaged in inequitable conduct, discuss whether certain information was material to a pending patent application, or otherwise provide legal conclusions on 'substantive issues of patent law.'" *Brigham*, 2010 WL 3907490, at *2. Dr. Gonsalves's opinions on whether the prior art cumulative is likewise improper. *W.L. Gore & Assocs., Inc. v. C.R. Bard, Inc.*, No. CV 11-515-LPS-CJB, 2015 WL 12815314, at *4 (D. Del. Nov. 20, 2015) (excluding various patent law expert opinions, including opinions on materiality of prior art and if it was cumulative to other information submitted to the PTO).

While every case is different, and while every *Daubert* motion considered on its merits, it is worth a mention that another court has previously barred Dr. Gonsalves from offering similar opinions. *See* Ex. D, *Applied Cap., Inc. v. ADT Corp.,* No. 1:16-CV-00815, 2021 WL 1339379, at *3 (D.N.M. Apr. 9, 2021) (excluding testimony of Dr. Gonsalves involving his "purported conclusions with respect to [the] topics" of "patent rules, procedure, and terminology, testimony about the patents, and evidence related to prosecution history" because "testimony that invades the province of the factfinder is not appropriate.").

Thus, the Court should exclude paragraphs 28-125 and 131-149 of Dr. Gonsalves' opening report and paragraphs 138-178 of Dr. Gonsalves' reply report, and preclude his testimony on any issue, as an improper attempt to instruct the Court on the applicable law and to offer legal analysis and conclusions about substantive issues of the case.

2. Dr. Gonsalves' Opinions on Alleged Intent to Deceive the PTO Are Likewise Improper As a Matter of Law

Dr. Gonsalves' opinions regarding the alleged intent of Mr. McIntosh to deceive the PTO should also be excluded as improper, given that they are also based on speculative and unreliable grounds, and where Dr. Gonsalves has no special expertise in divining the intent of anyone.

"[E]xpert witnesses are not permitted to testify regarding intent, motive, or state or mind, or evidence by which such state of mind may be inferred." *AstraZeneca*, 2012 WL 6043266, at *2 (citations and quotation marks omitted); *see also In re Rosuvastatin Calcium Pat. Litig*., No. CIV. 07-359-JJF-LPS, 2009 WL 4800702, at *8 (D. Del. Dec. 11, 2009) (excluding expert opinions as to evidence of state-of-mind or intent to deceive the PTO by the patentee); *Shire Viropharma*, 2021 WL 1227097, at *6 (excluding portions of expert testimony on subjective motivations or state of mind); *Greatbatch Ltd. v. AVX Corp*., No. CV 13-723-LPS, 2017 WL 3176179, at *2 (D. Del. July 20, 2017), *aff'd*, 813 F. App'x 609 (Fed. Cir. 2020) (striking expert opinions as to the state of mind and intent). This is precisely what Dr. Gonsalves seeks to do.

For example, Dr. Gonsalves's reports include his wholly subjective opinions that: (a) "Mr. McIntosh failed to provide any explanation for filing a Declaration that ***he knew was false*** other than that he ***intended to deceive*** the PTO ... Mr. McIntosh set forth no other reasonable inference that can be drawn except that ***he intended to deceive the PTO*** to overcome the cited prior art and obtain allowance of his patent" (Ex. A ¶ 135; *see also* Ex. B ¶ 146 appearing on page 8); (b) "Mr. McIntosh failed to provide any explanation for his failure to disclose the Milwaukee Tool prior art saws, including model 6225, other than that ***he intended to deceive*** the PTO" (Ex. A ¶ 146; *see also* Ex. B ¶ 164); (c) "Mr. McIntosh failed to provide any explanation for withholding this material prior art other than ***having an intent to deceive*** the PTO in order to obtain his patent" (Ex. A ¶ 147; *see also* Ex. B ¶ 165); (d) "Mr. McIntosh thus ***understood*** that a focus of his claimed invention was on the ability to use the bandsaw with one hand ... [yet] Mr. McIntosh withheld material prior art ... Mr. McIntosh provided no other reasonable inference from his failure to disclose these prior art bandsaws, such as the 6225, other than that ***he intended to deceive the PTO*** and withhold material prior art to obtain his patent" (Ex. A ¶ 148; *see also* Ex. B ¶ 166); and others (emphasis added).

Dr. Gonsalves is not the finder of fact and has no special expertise with regard to any of these opinions. His opinions regarding Mr. McIntosh's alleged state of mind or intent to deceive the PTO should be excluded. *See, e.g.*, *Victaulic Co. v. ASC Engineered Sols., LLC*, No. CV 20-887-GBW, 2022 WL 17250376, at *8 (D. Del. Nov. 28, 2022) (excluding "expert testimony as to intent, motive, or state of mind [as it] offers no more than the drawing of an inference from the facts of the case, which merely substitutes the expert's judgment for the jury's and would not be helpful to the jury" and "its probative value is substantially outweighed by a danger of . . . wasting time, or needlessly presenting cumulative evidence") (internal citations and quotation marks omitted); *see also In re Rosuvastatin Calcium Pat. Litig.*, No. CIV. 07-359-JJF-LPS, 2009 WL 4800702, at *8 (D. Del. Dec. 11, 2009), report and recommendation adopted, No. CIV.A 07-805-JJF, 2010 WL 661599 (D. Del. Feb. 19, 2010) (excluding expert arguments, assumptions, and inferences as to supposed state of mind or intent to deceive the PTO); *Shire Viropharma*, 2021 WL 1227097, at *5 ("[E]xpert witnesses are not permitted to testify regarding intent, motive, or state of mind, or evidence by which such state of mind may be inferred . . . the question of intent constitutes a classic jury question and not one for experts.") (internal citations and quotation marks omitted).

VII. CONCLUSION

For the foregoing reasons, Persawvere respectfully requests the Court exclude Dr. Gonsalves' opinions in which he regarding the governing law (including on the issues of inequitable conduct and the duty of candor), and opinions regarding any subjective issues, including alleged intent, motive, or state of mind to deceive the Patent Office, including the opinions in paragraphs 28-125 and 131-149 of Dr. Gonsalves' opening report and paragraphs 138-178 of Dr. Gonsalves' reply report.

Dated: July 21, 2023

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EXHIBIT 60

THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PERSAWVERE, INC., Plaintiff, v. MILWAUKEE ELECTRIC TOOL, CORPORATION, Defendant.	C.A. No. 1:21-cv-00400-GBW **JURY TRIAL DEMANDED** [redacted]

DEFENDANT MILWAUKEE ELECTRIC TOOL CORPORATION'S OPPOSITION BRIEF TO PLAINTIFF'S MOTION TO EXCLUDE EXPERT TESTIMONY OF DR. GREGORY GONSALVES

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Persawvere's *Daubert* motion to exclude the opinions of Milwaukee's inequitable conduct expert Gregory Gonsalves, Ph.D. is long on rhetoric and short on substance. Persawvere purports to transform Dr. Gonsalves's expert opinion regarding Patent Office procedures and prosecution of the application that led to the patent-in-suit into an opinion regarding patent law and an opinion regarding the ultimate issue of inventor Scott McIntonsh's intent to deceive the Patent Office. But Dr. Gonsalves does not opine on these issues because they are generally within the province of the fact-finder, which for inequitable conduct, is the Court. Dr. Gonsalves does cite law for background and to frame his analysis of how Patent Office procedures have been applied—a proper and common procedure in expert reports. Dr. Gonsalves also opines regarding materiality and the underlying inferences giving rise to an intent to deceive—something experts regarding inequitable conduct are permitted to do in this District and elsewhere. As such, Persawvere's motion is ultimately based on a mischaracterization of Dr. Gonsalves's intended testimony. Because Dr. Gonsalves will not invade the province of the Court as fact-finder, the Court should deny Persawvere's *Daubert* motion and allow Dr. Gonsalves to testify.

I. Dr. Gonsalves Should Be Permitted to Testify As an Expert Regarding Patent Office Procedures, Prosecution History, and Underlying Materiality Issues

Federal Rule of Evidence 702 governs testimony by experts, and provides that a qualified expert may testify in the form of an opinion or otherwise if "specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue." Trial courts have broad discretion in determining whether to admit expert testimony. *See United States v. Velasquez*, 64 F.3d 844, 847-48 (3d Cir. 1995).

Here, there is no dispute that the Dr. Gonsalves—a former administrative patent judge and attorney with extensive experience practicing before the Patent Trial and Appeal Board at the United States Patent and Trademark Office ("Patent Office")—has specialized knowledge

regarding in patents, the patent application process, and the policies, practices and procedures of the Patent Office. *See, e.g.*, D.I. 138-1 ("Mot."), Ex. A ("Opening Rpt."), ¶¶ 6-8. Persawvere does not appear to meaningfully dispute this fact. Indeed, Persawvere's Motion is based solely on purported flaws with Dr. Gonsalves offering legal opinions regarding case law or an intent to deceive. But numerous paragraphs of Dr. Gonsalves' Opening Report do not even mention these issues. *See id.*, ¶¶ 1-38, 40, 44-62, 64-65, 67-74, 76-81, 81-102, 112-118, 126-133, 136-143. Accordingly, there is no basis for the Court to exclude Dr. Gonsalves from offering the opinions set forth in these paragraphs.

For the challenges Persawvere does raise to Dr. Gonsalves's opinions—namely that he proffers legal opinions and that he impermissibly opines regarding intent to deceive—Persawvere mischaracterizes the scope and purpose of his opinions, and fails to demonstrate that Dr. Gonsalves's opinions and anticipated testimony will not be helpful to the Court.

A. Dr. Gonsalves Does Not Purport to Offer Opinions Regarding Legal Standards and Case Law.

As Persawvere acknowledges, Dr. Gonsalves provides opinions regarding "United States patent practice and procedures" (Mot. at 4 (quoting Opening Rpt., ¶ 1)). There is nothing improper about such opinions. Indeed, numerous courts in this District and elsewhere have held that expert witnesses may testify regarding Patent Office procedures, including many courts in cases Persawvere relies upon in its Motion. *See, e.g.*, *Brigham & Women's Hospital, Inc. v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 08-464, 2010 WL 3907490, at *2 (D. Del. Sept. 21, 2010) (denying motion to strike patent law expert's report except to the extent that it explains the Patent Office's practices and procedures because "the law permits experts in patent cases to offer such testimony"); *L'Oreal S.A. v. Revlon Consumer Prods. Corp.*, Civ. A. No. 98-424-SLR, 2008 WL 5868688, at *1 (D. Del. Sept. 30, 2008) (permitting patent law

expert to testify as to "matters of U.S. Patent and Trademark Office practice and procedure"); *see also Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1363 n.5 (Fed. Cir. 2008) ("[P]atent lawyers might offer testimony in contexts other than noninfringement and invalidity, such as patent office practice and procedure[.]").

In connection with explaining the Patent Office procedures, Dr. Gonsalves cites to background law and Patent Office procedures and manuals. *See* Opening Rpt., ¶¶ 28-81. He similarly cites legal standards for inequitable conduct and the duty of candor in order to place the factual background regarding these issues in context. *See id.*, ¶¶ 103-118. And, he provides pertinent legal background regarding how the Federal Circuit has interpreted the Patent Office disclosure requirements to frame his opinions regarding materiality. *See id.*, ¶¶ 103-118.

Persawvere interprets Dr. Gonsalves's discussion of this background legal framework to mean that he intends to offer opinions regarding "legal standards and case law," (Mot. at 6), but Persawvere is incorrect. Dr. Gonsalves does not intend to tell this Court what the law is—something the Court is already well-familiar with. As such, Persawvere's citation to a litany of authorities standing for the non-controversial point that the Court does not generally allow an expert to lecture regarding what the law is (*see id.* at 4-5) are inapposite to the scope of Dr. Gonsalves's opinions and anticipated testimony. Rather, paragraphs 28-81 and 103-125 of Dr. Gonsalves's Opening Report provide critical framework for the opinions he does proffer—not opinions regarding the law, but regarding Patent Office procedure, disclosure requirements, and issues bearing on materiality for the intent to deceive analysis. *See* Opening Rpt., ¶¶ 126-133. The Court should allow Dr. Gonsalves to provide legal background to inform his testimony, as needed.

Persawvere's contention that "another court has previously barred Dr. Gonsalves from offering similar opinions" does not undermine the propriety of his opinions in this case and is contrary to the very case Persawvere attached as Exhibit D to its motion. *See* Mot. at 8 (citing *Applied Cap., Inc. v. ADT Corp.*, No. 1:16-cv-00815, 2021 WL 1339379, at *3 (D.N.M. Apr. 9, 2021). In fact, the district court in *Applied Capital* expressly ***permitted*** Dr. Gonsalves to testify, finding that "[a]n explanation of patent rules, procedure, terminology, testimony about the patents, and evidence related to prosecution history may be relevant, reliable, and helpful[.]" *Id.* at *8. The same is true here: allowing Dr. Gonsalves to explain Patent Office procedure and provide the relevant legal and factual background to do so will be helpful. So too will allowing Dr. Gonsalves to explain the import of events that transpired during the prosecution of the patent-in-suit. *See Pfizer v. Teva Pharms USA, Inc.*, No. 04-754, 2006 WL 3041097, at *3 (D.N.J. Oct. 26, 2006) (permitting patent law expert "to testify as to Patent Office practice and procedure and factual information regarding the prosecution history of the applications that issued as the patents-in-suit"); *Minn. Mining & Mfg. Co. v. Appleton Papers, Inc.*, No. 4-95-786, 1998 WL 1054207, at *2 (D. Minn. June 24, 1998) (permitting patent law expert to offer "objective explanation of the patent application process, and the sequence of events that led to the [asserted] patent"). Indeed, the court in *Applied Capital* actually ***denied*** defendant's motion to exclude his testimony. *Applied Cap.*, 2021 WL 1339379, at *10.

B. Dr. Gonsalves's Opinions Regarding Materiality Underlying Intent to Deceive are Proper.

Persawvere criticizes Dr. Gonsalves for purportedly "divining the intent" of inventor Scott McIntosh. Mot. at 8; *see also id.* at 7 (seeking exclusion of paragraphs 126-145 of Dr. Gonsalves's Opening Report and paragraphs 138-177 of Dr. Gonsalves's Reply Report). However, Dr. Gonsalves does not purport to tell the Court Mr. McIntosh's intent—an issue the Court will

ultimately need to decide. Instead, Dr. Gonsalves opines—based on his expert knowledge of the Patent Office procedures and the record evidence—that Mr. McIntosh's conduct "failed to show any reasonable inference from filing a false declaration other than an intent to deceive." Opening Rpt., ¶¶ 134-135, 146-148. Put simply, Dr. Gonsalves did not see evidence to rebut an intent to deceive the Patent Office (for example, a declaration from Mr. McIntosh correcting his false statements to the Patent Office). In support of this inference, Dr. Gonsalves considers the materiality of underlying prior art and the impact of failing to disclose it in declaration submission as is required under Patent Office procedures. *See id.*, ¶¶ 136-145. Such testimony will assist the Court in assessing whether Mr. McIntosh withheld material prior art and had an intent to deceive.

Recognizing the helpfulness of expert testimony regarding this topic, courts routinely allow expert testimony regarding materiality issues, including the materiality of withheld prior art. *See, e.g.*, *Shire Viropharma Inc. v. CSL Behring LLC*, No. CV 17-414, 2021 WL 1227097, at *30 (D. Del. Mar. 31, 2021) (collecting cases and noting "numerous courts . . . have permitted non-technical, patent-law experts to testify as to the materiality prong of the inequitable conduct inquiry-an inquiry which is analyzed from the perspective of the Patent Office, and distinguishing this from cases holding it is error to opine on ultimate issue); *Liquid Dynamics Corp. v. Vaughan Co.,* No. 01-CV-6934, 2004 WL 2260626, *7 (N.D. III. Oct. 1, 2004) (denying patentee's motion *in limine* seeking to exclude testimony from patent attorney on whether a withheld reference would have been material under the reasonable examiner standard); *Aevoe Corp. v. AE Tech Co.*, No. 2:12-CV-00053-GMN, 2014 WL 4182343, at *2 (D. Nev. Aug. 20, 2014) ("In contrast to inquiries into infringement and validity, the materiality prong of the inequitable conduct inquiry is analyzed from the perspective of the PTO. . . . Accordingly, an appropriate expert on

this topic could be an individual who has knowledge of and experience with the procedures of the PTO. Often, such an individual will be an attorney with experience practicing before the PTO.").

For all of these reasons, Persawvere is incorrect when it asserted that Dr. Gonsalves opines that Mr. McIntosh intended to deceive the Patent Office (Mot. at 8). Rather, based on his expert knowledge regarding Patent Office procedures and prosecution and review of the underlying evidence, Dr. Gonsalves properly opined regarding reasonable inferences from the record evidence (and lack of evidence in the record to correct Mr. McIntosh's false statements). *See, e.g.*, Opening Rpt., ¶¶ 134-135, 146-150. It will be up to the Court to make the ultimate determination of whether there was an intent to deceive the Patent Office, and Dr. Gonsalves's expert opinions can aid the Court in reaching the correct conclusion.

II. Conclusion

For the foregoing reasons, the Court should allow Dr. Gonsalves to present his opinions and analysis to the Court, and should deny Persawvere's *Daubert* motion.

Dated: July 28, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies that on July 28, 2023, a copy of Defendant Milwaukee Electric Tool Corporation's Opposition Brief to Plaintiff's Motion to Exclude Expert Testimony of Dr. Gregory Gonsalves, which was filed under seal, was served via electronic mail on the following counsel of record:

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EXHIBIT 61

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PERSAWVERE, INC., Plaintiff, v. MILWAUKEE ELECTRIC TOOL CORPORATION, Defendant.	C.A. No. 21-400-GBW

PLAINTIFF PERSAWVERE, INC.'S REPLY BRIEF IN SUPPORT OF ITS *DAUBERT* MOTION TO EXCLUDE EXPERT TESTIMONY OF GREGORY GONSALVES, PH.D.

Dated: August 4, 2023

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I. INTRODUCTION

Milwaukee's opposition attempts to re-characterize improper legal opinions offered by Dr. Gonsalves to save his opinions from exclusion. Milwaukee, however, cannot ignore the ample caselaw that Plaintiff cited in its Opening Brief (D.I. 138) finding that testimony regarding patent law, including his interpretations of the legal standards for inequitable conduct and testimony on Mr. McIntosh's alleged intent to deceive the PTO, is impermissible. First, Dr. Gonsalves' legal opinions regarding PTO procedures and the state of inequitable conduct law are not helpful to the ultimate factfinder, this Court. Second, Dr. Gonsalves' speculation and subjective opinions on Mr. McIntosh's intent to deceive the PTO attempts to substitute Dr. Gonsalves' judgment for the Court's, which is improper. Milwaukee has failed to prove that any of Dr. Gonsalves' challenged testimony is proper under Federal Rule of Evidence 702.

II. DR. GONSALVES' SO-CALLED "FACTUAL BACKGROUND" TESTIMONY COVERING LEGAL STANDARDS AND CASE LAW SHOULD BE EXCLUDED

Milwaukee incorrectly contends that Dr. Gonsalves should be permitted to offer the Court self-serving summaries of legal standards and case law because these summaries are just "factual background" and "framework" regarding "opinions" about the inequitable conduct defense, including its two prongs—intent and materiality. Opp. at 3.[1] Simply put, what Milwaukee is arguing is that Dr. Gonsalves' offered testimony on the legal standards and case law are not legal opinions, but "facts." This is not the case and improper as a matter of law.

As this Court explained, for example, in *PureWick Corp. v. Sage Prod., LLC*—the case Milwaukee never responds to—"legal testimony on substantive issues of patent law or Patent Office procedure improperly substitutes the judgment of the expert for that of the Court." 2021 WL 2593338, at *1 (D. Del. June 24, 2021) (excluding a patent law expert's "instructions about patent

[1] Discussing D.I. 138-1, Ex. A (Gonsalves Op. Rpt.) ¶¶ 28-81, 103-125.

law, patent regulations and arguments about what patent practitioners purport to understand" as "unhelpful and inappropriate"). *See also AstraZeneca UK Ltd. v. Watson Lab'ys, Inc. (NV)*, 2012 WL 6043266, at *1 (D. Del. Nov. 14, 2012) (another case Milwaukee does not respond to, excluding the testimony of a legal expert, including his "descriptions of the law and instructions on the law" and "procedures at the PTO," as not helpful to the Court and improper) (citing cases); *Lannett Co. Inc. v. KV Pharm., Drugtech Corp.*, No. CV 08-338-JJF, 2009 WL 10657988, at *5 (D. Del. Mar. 9, 2009) (yet another case not addressed by Milwaukee in which similar legal expert opinions have been excluded as "usurp[ing] the role of the trial judge"). The result in this case should not be different—Dr. Gonsalves' testimony about legal standards and case law should be excluded.

Similarly, the remaining sections of Dr. Gonsalves' reports are nothing more than legal analysis and conclusions about alleged misconduct (surrounding the declaration by Mr. McIntosh), materiality of alleged misrepresentations to the Patent Office, and purported intent to deceive the Patent Office. D.I. 138-1, Ex. A (Gonsalves Op. Rpt.) ¶¶ 126-149; *see also* D.I. 138-2, Ex. B (Gonsalves Reply Rpt.) ¶¶ 138-178. When Dr. Gonsalves makes statements like "Mr. McIntosh's filing of a false Declaration before the PTO is thus material misconduct" (Ex. A, ¶ 133) or "Mr. McIntosh failed to show any reasonable inference from filing a false declaration other than an intent to deceive" (Ex. A, ¶ 149), he is making a legal conclusion in an attempt to substitute his judgment for the judgment of this Court. All of these statements are impermissible. *Brigham & Women's Hosp. Inc. v. Teva Pharms. USA, Inc.*, No. 08-464, 2010 WL 3907490, at *2 (D. Del. Sept. 21, 2010); *see also Flickinger v. Toys R Us-Delaware, Inc.*, 492 F. App'x 217, 224 (3d Cir. 2012) (noting that the Federal Rules of Evidence do not permit expert testimony as to legal conclusions).

Milwaukee also asserts that Dr. Gonsalves' testimony about "Patent Office [practice and] procedures" should be permitted. Opp. at 2-3. But since the inequitable conduct defense is to be tried before the bench trial in this case, PTO practices and procedures testimony will serve no useful purpose and would only waste the Court's and the parties' time. *See, e.g.*, *PureWick*, 2021 WL 2593338, at *1 (excluding expert testimony on substantive issues of patent law and Patent Office procedures); *AstraZeneca*, 2012 WL 6043266, at *2 (same). Likewise, Dr. Gonsalves' testimony about the prosecution history is improper. *AstraZeneca*, 2012 WL 6043266, at *1.

The cases which Milwaukee relies on in its opposition are inapposite. Opp. at 2-3. For example, in *L'Oreal S.A. v. Revlon Consumer Prod. Corp.*, the Court granted a motion *in limine* to limit the testimony of a patent law expert to "Patent and Trademark Office practice and procedure" only because this motion was unopposed. 2008 WL 5868688, at *1 (D. Del. Sept. 30, 2008). In *Sundance, Inc. v. DeMonte Fabricating Ltd.*, the Federal Circuit determined that a legal expert was not qualified to testify about infringement or validity, the topics which are not in dispute here. 550 F.3d 1356, 1361 (Fed. Cir. 2008). In *Brigham & Women's Hosp.*, this Court excluded the entirety of a patent law expert report "except to the extent that it explains the PTO's practices and procedures." 2010 WL 3907490, at *2. As evident from the Persawvere's opening brief, the *Brigham & Women's Hosp.* case is a rare exception and other legal precedents of this Court prove the opposite is more common practice in non-jury cases. *PureWick*, 2021 WL 2593338, at *1 (excluding testimony about PTO practices and procedures); *Corning Inc. v. SRU Biosystems*, No. CIV.A. 03-633 JJF, 2004 WL 5523178, at *1 (D. Del. Nov. 5, 2004) (same); *AstraZeneca*, 2012 WL 6043266, at *2 (same).

Finally, Milwaukee attempts to explain (unsuccessfully) why similar Dr. Gonsalves' testimony was excluded in another court. Opp. at 4 (discussing *Applied Cap., Inc. v. ADT Corp.*,

No. 1:16-CV-00815, 2021 WL 1339379 (D.N.M. Apr. 9, 2021)). The Court in the *Applied Cap.* case excluded Dr. Gonsalves' testimony "as to his purported conclusions" concerning materiality and intent—two prongs of inequitable conduct defense. *Applied Cap.,* 2021 WL 1339379, at *8. The Court only allowed his testimony as to patent rules, procedure, and terminology, because this testimony was found to be helpful to the jurors, to whom these topics are often foreign. *Id.* Here, Dr. Gonsalves will testify at a bench trial, negating any benefit the New Mexico district court saw for this testimony. Dr. Gonsalves' testimony as to PTO procedure and practice should be excluded along with his other legal opinions regarding inequitable conduct.

III. DR. GONSALVES' LEGAL OPINIONS ON INTENT TO DECEIVE THE PTO SHOULD BE EXCLUDED

Dr. Gonsalves' opinions on Mr. McIntosh's state of mind, including his "reasonable inferences" regarding the same, and the testimony regarding what Milwaukee calls "materiality underlying intent," should be excluded. *See* Mot. 8-10 (providing examples of Dr. Gonsalves' testimony where he opines on Mr. McIntosh's alleged intent to deceive by misrepresenting material information); *see generally* D.I. 138-1, Ex. A ¶¶ 134-149; D.I. 138-2, Ex. B ¶¶ 138-178. This type of testimony is impermissible. *See* Mot. at 9-10 (citing cases). Here, it is telling that the Milwaukee agrees that it is for the Court to decide the issue of intent to deceive and does not even respond to many of the cases cited in Persawvere's opening brief. Opp. at 4-5.

IV. CONCLUSION

For the foregoing reasons, Persawvere respectfully requests the Court exclude Dr. Gonsalves' opinions regarding the governing law and any subjective issues, such as alleged intent to deceive the Patent Office, including the opinions in paragraphs 28-125 and 131-149 of Dr. Gonsalves' opening report and paragraphs 138-178 of his reply report.

Dated: August 4, 2023

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EXHIBIT 62

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TQ DELTA, LLC, Plaintiff, v. DISH NETWORK CORPORATION, *et al.*, Defendants.	:	Civil Action No. 15-614-RGA

SPECIAL MASTER ORDER #12 – RULING ON DISH DEFENDANTS' MOTION TO COMPEL PLAINTIFF TQ DELTA, LLC TO DISCLOSE THE HYPOTHETICAL CLAIM RELEVANT TO ITS DOCTRINE OF EQUIVALENTS INFRINGEMENT ALLEGATION AND RESPONSIVE TO DISH'S ENSNAREMENT DEFENSE

I. INTRODUCTION

Pending before the Special Master is Defendants DISH Network Corp., DISH Network LLC, DISH DBS Corp., and DISH Technologies L.L.C.'s (collectively "DISH") motion to compel Plaintiff TQ Delta, LLC ("TQ Delta" or "Plaintiff") to disclose the hypothetical patent claim relevant to its doctrine of equivalents infringement allegation and responsive to DISH's ensnarement defense (D.I. 381) (the "Motion").[1] On January 25, 2022, TQ Delta submitted its answering brief opposing the Motion ("Answering Brief" or "Ans. Br."). On January 31, 2022, the Special Master heard oral argument on the Motion. Having considered the written submissions of the parties and oral argument from counsel, and for the reasons set forth more fully below, the Special Master hereby orders that the Motion is GRANTED IN PART and DENIED IN PART.

[1] In support of the Motion, DISH lodged upon the Special Master an Opening Letter Brief dated January 18, 2021 ("Opening Brief" or "Op. Br.").

II. BACKGROUND AND RELEVANT PROCEDURAL POSTURE

In the present action, TQ Delta alleges that DISH infringed two (2) of TQ Delta patents, including U.S. Patent No. 8,718,158 ("the '158 patent"). Specifically, TQ Delta contends that DISH's products infringe the "determining a phase shift for the carrier signal" limitation of claim 1 of the '158 patent both literally and under the doctrine of equivalents theory. (Op. Br., Ex. 7 (TQ Delta's First Supplemental Claim Charts) at 19-21). DISH asserts an ensnarement defense claiming that TQ Delta's doctrine of equivalents infringement theory is "improper because it 'ensnare[s]' the prior art." (Op. Br. at 1 (citing Ex. 8 (DISH's Supplemental Objections and Responses to Plaintiff's Sixth Set of Rule 33 Interrogatories (Nos. 12 and 13)) at 8-10).

The Motion asserts that, since DISH asserted its ensnarement defense, TQ Delta has not identified a hypothetical claim that covers the alleged equivalent without ensnaring the prior art. (Op. Br. at 1). Thus, DISH seeks an order requiring TQ Delta to disclose a hypothetical patent claim for purposes of its doctrine of equivalents infringement allegations. (D.I. 381). DISH argues that TQ Delta is required to disclose a hypothetical patent claim that is relevant to its doctrine of equivalents theory because "[d]isclosure of a hypothetical claim is the only reliable method for testing whether the [doctrine of equivalents] theory ensnares the prior art." (Op. Br. at 3). DISH alternatively argues that, to the extent TQ Delta does not utilize the hypothetical claim methodology, TQ Delta should be required to disclose its "complete factual and legal bases for its [doctrine of equivalents theory] which requires a description of its contentions regarding why the theory does not ensnare the prior art[.]" (*Id.*)

TQ Delta contests the Motion on three bases: (i) DISH had no basis to file the Motion because there is no written discovery request that entitles DISH to this discovery; (ii) a hypothetical claim analysis is not required because it is not the only method by which a court can assess whether

a doctrine of equivalents theory ensnares the prior art; and (iii) DISH's request for a hypothetical claim is premature. (Ans. Br. at 1-3).

III. ANALYSIS

It is well-established that "[a] doctrine of equivalents theory cannot be asserted if it will encompass or 'ensnare' the prior art." *Jang v. Boston Scientific Corp.*, 872 F.3d 1275, 1285 (Fed. Cir. 2017) (citing *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1322 (Fed. Cir. 2009)). In testing ensnarement, "[a] hypothetical claim *may be* constructed to literally cover the accused device." *Interactive Pictures Corp. v. Infinite Pictures, Inc.*, 274 F.3d 1371, 1380 (Fed. Cir. 2001) (emphasis added); *see also DePuy Spine, Inc.*, 567 F.3d at 1324 ("A helpful first step in an ensnarement analysis is to construct a hypothetical claim that literally covers the accused device."). However, there is no requirement that the patentee asserting a doctrine of equivalents infringement allegation produce a hypothetical claim. *See Jang v. Boston Scientific Corp.*, 872 F.3d 1275, 1287, n.4 (Fed. Cir. 2017) ("The hypothetical claim analysis is not the only method in which a district court can assess whether a doctrine of equivalents theory ensnares the prior art."); *Conroy v. Reebok Int'l*, 14 F.3d 1570, 1577 (Fed. Cir. 1994) (comparing the prior art with a single element of the accused device in an attempt to determine the extent to which prior art limits the application of the doctrine of equivalents rather than performing a hypothetical claim analysis); *Agrofresh, Inc. v. Essentiv LLC*, 2020 WL 7024867, at *15 (D.Del. Nov. 30, 2020) (recognizing "that courts are not constrained to a hypothetical claim analysis."). Thus, while a hypothetical claim analysis is one way to assess whether TQ Delta's doctrine of equivalents theory ensnares the prior art, it is not the *only* way. See *id.*

Accordingly, the Special Master denies the Motion to the extent that it seeks to require TQ Delta to produce a hypothetical claim as the sole means to determine whether an equivalent would

impermissibly ensnare the prior art. The Special Master grants the Motion to the extent that it seeks to require TQ Delta to disclose the complete factual and legal bases in support of its doctrine of equivalents infringement allegation. Such disclosure must occur before the close of fact discovery and the deadline for the production of expert reports, as applicable to the nature and contents of the disclosure.[2]

Although the Special Master recognizes TQ Delta's ability to make its own strategic decision and is not compelling TQ Delta to produce a hypothetical claim, the Special Master does note the risk that TQ Delta takes in pursuing its doctrine of equivalents theory in light of DISH's ensnarement defense without a hypothetical claim. It is the accused infringer's burden to come forward with prior art, but it is the patentee's burden to prove that it is entitled to the range of equivalents it seeks. *Jang, 872 F.3d at 1287; Agrofresh, Inc*, 2020 WL 7024867, at *15. The patentee has the burden to prove that its asserted range of equivalents do not ensnare the prior art. In other words, the patentee asserting the doctrine of equivalents infringement allegation bears the risk of not producing a properly drafted hypothetical claim in proving that the claim is patentable over the prior art. *See id.* However, knowing the risk of possibly not being able to meet its burden on its doctrine of equivalents infringement theory without producing a hypothetical claim, TQ Delta is free to take that calculated risk if it so chooses.

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[2] Despite the timing of the Court's consideration of DISH's ensnarement defense, this Court routinely prohibits trial by ambush and requires the full disclosure of all factual and legal contentions during discovery. *See Intell. Ventures I LLC v. AT&T Mobility LLC*, 2017 WL 658469, at *4 (D. Del. Feb. 14, 2017) (striking Plaintiff's doctrine of equivalents contentions on the basis that they were "deficient" and "highly prejudicial to Defendants, who lack[ed] notice of how their accused products purportedly infringe under the doctrine of equivalents."). During oral argument on January 31, 2022, counsel for TQ Delta represented to the Special Master that it has already disclosed the factual and legal bases for its doctrine of equivalents infringement allegation.

IV. CONCLUSION

For all of the foregoing reasons, the Motion is GRANTED IN PART and DENIED IN PART. The Motion is granted to the extent that it seeks to compel TQ Delta to produce the complete factual and legal bases in support of its doctrine of equivalents infringement allegation before the close of fact discovery and the deadline for the production of expert reports, as applicable to the nature and contents of the disclosure. The Motion is denied to the extent that it seeks to require TQ Delta to produce a hypothetical claim as the sole means to determine whether an equivalent would impermissibly ensnare the prior art.

ENTERED this 2nd day of February, 2022.

Gregory B. Williams (#4195)
Special Master

SO ORDERED this _____ day of _____, 2022.

UNITED STATES DISTRICT COURT JUDGE

EXHIBIT 63

No. 17-1866

IN THE UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

MEDTRONIC, INC. & CONSOLIDATED SUBSIDIARIES

Appellee

v.

COMMISSIONER OF INTERNAL REVENUE

Appellant

ON APPEAL FROM THE DECISION
OF THE UNITED STATES TAX COURT

BRIEF FOR THE APPELLANT

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SUMMARY OF THE CASE AND REQUEST FOR ORAL ARGUMENT

This federal income-tax case concerns the proper means to determine an arm's-length price for an intercompany transfer of high-profit intangibles by a U.S. corporation (Medtronic) to its controlled foreign subsidiary under I.R.C. § 482 and the related regulations. After a trial, the Tax Court rejected the transfer prices proffered by both parties, and determined a price utilizing Medtronic's transfer-pricing method. The Commissioner contends that the court erred as a matter of law because its adoption of Medtronic's transfer-pricing method, and its rejection of the Commissioner's method, conflict with the relevant rules. A remand is required so that the Tax Court may reevaluate the best transfer-pricing method. Alternatively, the Commissioner contends that the case should be remanded so that certain adjustments may be made to the transfer price adopted by the Tax Court.

Pursuant to Eighth Circuit Rule 28A(i)(1), counsel for the Commissioner respectfully inform the Court that they believe that oral argument may be beneficial in this case, and suggest that 20 minutes per side would be adequate to address the issues.

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GLOSSARY

Add	Commissioner's Separate Addendum
App	Commissioner's Separate Appendix
CPM	comparable profits method
CUT	comparable uncontrolled transaction
I.R.C.	Internal Revenue Code
IRS	Internal Revenue Service
MOU	Memorandum of Understanding
Op/Add	Tax Court's opinion as contained in the Separate Addendum filed with the Commissioner's opening brief

JURISDICTIONAL STATEMENT

Appellee Medtronic, Inc. (Medtronic), a U.S. corporation and common parent of a multinational group of consolidated U.S. corporations and foreign affiliates, filed consolidated federal income-tax returns for its 2005-2006 tax years. (Op/Add7.) In 2011, it petitioned the Tax Court for a redetermination of the deficiencies determined by the Commissioner of Internal Revenue for those years. (App2.) The Tax Court had jurisdiction under Sections 6213(a) and 7442 of the Internal Revenue Code (26 U.S.C.).

On January 25, 2017, the Tax Court entered its decision. (Add145.) That decision disposed of all the parties' claims. This Court has jurisdiction over the Commissioner's appeal under I.R.C. § 7482(a)(1). The Commissioner's notice of appeal was timely filed on April 21, 2017 (App599), within the 90 days allowed by I.R.C. § 7483. *See* Fed. R. App. P. 13(a)(1).

STATEMENT OF THE ISSUE

This case concerns a U.S. corporation that developed highly profitable technical information, patents, regulatory approvals, and other intangibles regarding certain medical devices, and then licensed

those intangibles to an affiliated manufacturing operation in Puerto Rico. Although the U.S. corporation controlled the Puerto Rican affiliate, the affiliate's income was not subject to U.S. tax. The question presented is:

Whether the amount of royalties that the Puerto Rican affiliate paid to the U.S. corporation for the use of its intangibles was a fair, arm's-length amount or whether it was artificially low, thus failing to clearly reflect the U.S. corporation's true income.

The most apposite authorities are:

I.R.C. § 482

§ 1.482-1[1]

§ 1.482-4

§ 1.482-5

G.D. Searle & Co. v. Commissioner, 88 T.C. 252 (1987)

Podd v. Commissioner, 1998 WL 345513 (T.Ct. 1998)

Seagate Tech., Inc. v. Commissioner, 102 T.C. 149 (1994)

Sundstrand Corp. v. Commissioner, 96 T.C. 226 (1991)

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[1] All "§" references not prefaced by "I.R.C." are to the Treasury Regulations codified at 26 C.F.R., as in effect during 2005-2006. *See* Add147-185. Dollar figures are approximations.

STATEMENT OF THE CASE

A. Procedural overview

This case involves a multinational company (Medtronic) that priced intercompany transactions in a manner that did not clearly reflect its income subject to U.S. taxation. Section 482 of the Internal Revenue Code is designed to prevent such behavior and allows the Commissioner to reallocate income among related parties by determining the arm's-length price for intercompany transactions. In 2010, the Commissioner issued Medtronic a notice of deficiency for tax years 2005-2006 that increased its taxable income by $500 million for 2005 and $750 million for 2006 to reflect an arm's-length result for intercompany transactions between Medtronic's U.S. companies and its Puerto Rican subsidiary (Medtronic-P.R.) with respect to U.S. sales of certain products.[2] (App260.) Medtronic then filed a petition in the Tax Court challenging the deficiencies and seeking an overpayment for 2005 and 2006. (Op/Add73.) After a trial, the court concluded that neither

[2] The Commissioner's amended Answer increased these adjustments to $550 million (2005) and $810 million (2006). (App546-547.) The Tax Court erroneously referred to these income adjustments as tax "deficiencies." (Op/Add71.)

party had determined an arm's-length price for the transaction at issue (an intercompany license of technology intangibles), made adjustments to Medtronic's transfer-pricing method, and entered a decision that largely affirmed Medtronic's tax-reporting position by increasing income allocable to its U.S. operations by only $29 million. (App598.) The Commissioner has appealed.

B. Background: Transfer pricing

U.S. corporations operating through related enterprises, including affiliated foreign corporations, have long attempted to manipulate their internal allocations and transactions in order to avoid U.S. income. For example, a U.S. corporation could sell a product that was generated through the joint efforts of U.S. and Puerto Rican subsidiaries, but allocate most of the costs to the U.S. companies and most of the income to the Puerto Rican subsidiaries, thereby artificially lowering its income subject to U.S. taxation. To combat such abuse, and to ensure that transactions between related parties reflect economic reality, Congress — for almost 100 years[3] — has given the IRS the "broad authority" to

[3] *See* 4 Bittker & Lokken, *Fed'l Taxation of Income, Estates & Gifts* ¶79.1 (3d ed. 2003).

evaluate the pricing of transactions between commonly controlled parties (Op/Add76), and to allocate certain tax items (including gross income) "if [it] determines that such . . . allocation is necessary in order to prevent evasion of taxes or clearly to reflect the income of any such" entities. I.R.C. § 482. Under regulations implementing Section 482, taxable income of commonly controlled entities will be determined as if they had conducted their affairs in the manner of unrelated entities "dealing at arm's length." § 1.482-1(b)(1).

This case concerns the transfer of the right to use intangibles between related parties. For many years, the arm's-length price for such transfers was determined primarily by reference to transfers between unrelated parties involving "the same or similar intangible property under the same or similar circumstances." 26 C.F.R. § 1.482-2(d)(2)(ii) (1985). By the mid-1980s, however, Congress became concerned that this approach was insufficient to properly allocate income when related parties transferred "high-profit" intangibles because there were no comparable transactions for such transfers. Joint Committee on Tax'n, G*en'l Explanation of the Tax Reform Act of 1986*, JCS-10-87, at 1014-1016 (1987).

In particular, and as relevant to this case, Congress was concerned about taxpayers "transferring relatively high profit intangibles to Puerto Rico" without requiring the Puerto Rican affiliate to pay the U.S. affiliate a royalty that was "commensurate with the income attributable to the intangible." H.R. Rep. No. 99-426, at 425 (1985). As Congress explained, there "is a strong incentive for taxpayers to transfer intangibles to related [corporations] in a low tax jurisdiction, particularly when the intangible has a high value relative to manufacturing or assembly costs." *Id.* at 423.

To remedy this problem, Congress added the following sentence to Section 482 in 1986:

> In the case of any transfer (or license) of intangible property (within the meaning of section 936(h)(3)(B)), the income with respect to such transfer or license shall be commensurate with the income attributable to the intangible.

Tax Reform Act of 1986, P.L. 99-514, § 1231(e)(1) (codified at I.R.C. § 482). The stated "objective" of the 1986 amendment — known as the commensurate-with-income requirement — was to ensure "that the division of income between related parties reasonably reflect the relative economic activity undertaken by each." H.R. Rep. No. 99-841, at II-637 (1986) (Conf. Rep.). Congress also directed Treasury to

evaluate its transfer-pricing regulations and consider alternative methods for pricing intercompany intangible transfers that did not depend on identifying comparable transfers between unrelated parties. *Id.* at II-638.

In response, Treasury overhauled its transfer-pricing regulations. Intercompany Transfer Pricing Regulations Under Section 482, 59 Fed. Reg. 34,971 (1994). The changes were directed at remedying the prior inappropriate pricing of high-profit intangibles by reference to transactions that were not truly comparable. To remedy the problem, the 1994 regulations heightened the comparability standards for reliance on purportedly comparable transactions between unrelated parties, and provided alternative, profit-based methods that, in many instances, could more reliably provide an arm's-length price.

The 1994 regulations provide several alternative methods for determining an arm's-length price for intercompany transactions, and require that the "best method" — that is, the method that provides the most reliable arm's-length result for the transaction at issue — be utilized. § 1.482-1(c). For intercompany transfers or licenses of intangible property (such as patents or trade secrets), the alternative

methods include (as relevant to this appeal) the comparable-uncontrolled-transaction method (CUT), § 1.482-4(c), and the comparable-profits method (CPM), § 1.482-5. *See* § 1.482-4(a) (listing methods).

The CUT method determines the arm's-length consideration for the related-party transfer (referred to as the "controlled transaction") based on the price utilized in a transaction between unrelated parties (referred to as the "uncontrolled transaction"), and is limited to situations where the intangibles transferred, and the circumstances of the transfer, are comparable. § 1.482-4(c). The regulations list numerous comparability factors that must be considered before a transaction may be treated as a CUT. § 1.482-4(c)(2). Differences between the controlled and uncontrolled transactions may be accounted for by making appropriate adjustments to the price in the uncontrolled transaction, so long as the number and magnitude of the adjustments are small enough to be reliable. § 1.482-1(c)(2)(i).

Unlike the CUT method, the CPM does not depend on finding a comparable uncontrolled transaction, which may not exist for high-profit intangibles. Instead, the CPM determines the arm's-length

consideration for a controlled transaction "based on objective measures of profitability (profit level indicators) derived from uncontrolled taxpayers that engage in similar business activities under similar circumstances." § 1.482-5(a). This method "relies on the general principle that similarly situated taxpayers will tend to earn similar returns." 59 Fed. Reg. at 34,985. The test whether a company is "comparable" under the CPM is less "strict" than whether a transaction is "comparable" under the CUT or other transaction-based methods, and "diversity in terms of the functions and products is permitted." *Id.* at 34,974. The CPM generally is applied to the participant in the controlled transaction with the simplest and most easily compared operations (the tested party). § 1.482-5(b)(2).

The regulations demonstrate (through an example) how the CPM may be used to price controlled transfers of intangibles. § 1.482-5(e), Ex. 4. Assume U.S. Company licenses intangibles to Foreign Subsidiary, which uses them to manufacture goods that it sells to other subsidiaries of U.S. Company. Under the CPM, royalties paid to U.S. Company by Foreign Subsidiary may be tested by comparing the operating profit reported by Foreign Subsidiary to that of companies

engaged in similar manufacturing operations, based, for example, on their rates-of-return on operating assets. If Foreign Subsidiary's operating profit is different from that of the comparable companies, the royalties must be adjusted to an amount that produces a comparable operating profit for Foreign Subsidiary.

When promulgating the 1994 regulations, Treasury speculated that the CPM would be "a method of last resort." 59 Fed. Reg. at 34,985. In practice, however, the CPM is the "primary" method used by both Treasury and taxpayers in Advance Pricing Agreements for transfers of tangible and intangible property. IRS Announcement 2016-12, 2016-14 I.R.B. 589. *See* App779, 1079-1080.

Ultimately, the details of the transfer-pricing methodology are less important than the reasonableness of the result. (Op/Add117-118.) For transfers of intangibles, the result "must be commensurate with the income attributable to the intangible," as Section 482 requires. § 1.482-4(a). "Looking at the income related to the intangible and splitting it according to relative economic contributions" by the related parties implements the arm's-length standard because it is "consistent with what unrelated parties do." Notice 88-123, 1988-2 C.B. 458, 472. Thus,

to evaluate the reasonableness of a price for an intercompany transfer of intangibles, one must compare the functions performed and risks borne by the related parties and determine their relative contributions in generating the profit at issue.

C. Medtronic's operations

Medtronic is a leading medical device company that is headquartered in the United States and has operations and sales worldwide. (Op/Add7.) As relevant here, Medtronic produced and marketed implantable cardiac pulse generators and neurological stimulators (Devices) and related medical-therapy-delivery devices (Leads) (collectively "Devices/Leads") to U.S. customers.[4] *See* App429-440 (describing Devices/Leads).

Medtronic's Devices/Leads business engages several different functions within the Medtronic organization: research and development, clinical trials and regulatory approvals, manufacturing, marketing, and sales and distribution. (Op/Add13-21, 48-55; App334-365.) The clinical

[4] The cardiac Devices deliver electrical impulses to stimulate the heart; the neurological Devices deliver electrical impulses to the nervous system to reduce pain; and the Leads connect the cardiac and neurological Devices to the heart and nervous system, respectively. (Op/Add40-43, 51-52; App429-433.)

and regulatory functions are required because the Devices/Leads are Class III devices. The FDA classifies all medical devices into Class I, II, or III, and applies the highest level of control to Class III devices, requiring those devices to go through a premarket-approval process prior to distribution in the United States. (App549-553.)

During 2005-2006, all the functions required to produce and market the Devices/Leads were performed by Medtronic's U.S. operations (Medtronic and its consolidated U.S. subsidiary, Med USA[5]), except for a portion of the manufacturing that was performed by its Puerto Rican operations (Medtronic-P.R.) (discussed below). (Op/Add13-21, 48-55; App334-365, 924.) Although Medtronic-P.R. assisted its U.S. affiliates with some of the non-manufacturing functions, the responsibility for those functions rested with Medtronic's U.S. operations. (Op/Add13, 15-17, 27, 30, 44, 46-50, 110; App841, 895-899.) During the years at issue, Medtronic's U.S. operations incurred 88.7% of the external costs (*i.e.*, costs excluding intercompany costs) for

[5] Med USA performed Medtronic's sales-and-distribution function. (Op/Add20-21.)

the Devices/Leads, and Medtronic-P.R. incurred the remaining 11.3%. (App841-842.)

Much of Medtronic's costs were incurred in developing the intangible property required to produce and sell the Devices/Leads, including know-how, patents, regulatory approvals, and trade secrets. (App327, 342-347, 366.) To create those intangibles, Medtronic invested heavily in research and development. (Op/Add13-16; App327, 336-340.) Moreover, as noted above, the Devices/Leads are Class III devices, which required Medtronic to invest in a "rigorous, costly, and time consuming" premarket-approval process. (Op/Add7-9, 16; App342-347.)

Product quality is essential to Medtronic's ability to promote and sustain its brand. (Op/Add10; App328.) Accordingly, Medtronic emphasizes quality throughout its operations, and has created quality manuals and policies for each of its business units. (Op/Add14-15; App328-329, 359-361.) Although concerns about quality affects all functional areas, it has the greatest impact on Medtronic's research and development, component manufacturing, and finished-product manufacturing. (App335.)

D. Manufacturing of Devices/Leads

During 2005-2006, Medtronic's manufacturing function was split between its U.S. and Puerto Rican operations. (Op/Add17-24, 53-55; App335.) Medtronic's U.S. manufacturing divisions made the critical and complex components for the Devices/Leads. (Op/Add17-20; App350-352.) Medtronic-P.R. then incorporated those components into the finished Devices/Leads that it manufactured.[6] (Op/Add20-21; App353-358.)

Medtronic's U.S. component-manufacturing operations and its Puerto Rican finished-product-manufacturing operations engaged in many of the same activities, including product testing, improving the manufacturing processes, and employing highly skilled workers. (Op/Add17-19; App554-558, 1001-1016, 1020-1053.) In particular, both manufacturing operations were responsible for, and strove to

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[6] Medtronic has manufactured products in Puerto Rico since the 1970s. (Op/Add22.) Prior to 2001, its Puerto Rican operations were organized as "possession corporations," which provided Medtronic certain U.S. tax benefits under I.R.C. § 936. In 2001, Congress began to phase out those benefits, and, in response, Medtronic reorganized its Puerto Rican operations as Medtronic-P.R., a Cayman Islands corporation. (Op/Add21-23.) Medtronic-P.R.'s income was subject to no U.S. tax and almost no Puerto Rican tax. (Op/Add24.)

implement, Medtronic's quality standards. (Op/Add15-20; App359-361, 548, 577-584, 1011-1014, 1017-1019, 1026.)

E. Intercompany agreements

During 2005-2006, the following intercompany agreements created by Medtronic were in effect with regard to its production of Devices/Leads (Op/Add74-76):

- components supply agreement: Medtronic's U.S. manufacturing divisions provided Medtronic-P.R. the critical components needed to manufacture the Devices/Leads. (Op/Add37-38.)
- distribution agreement: Med USA distributed and sold the Devices/Leads that Medtronic-P.R. manufactured. (Op/Add38.)
- trademark license: Medtronic granted Medtronic-P.R. the right to use Medtronic's trademarks in exchange for a royalty. (Op/Add39.)
- technology licenses: Medtronic granted Medtronic-P.R. the exclusive right to use Medtronic's clinical data, designs, know-how (both existing technical manufacturing

information and future improvements), patents, regulatory approvals, and trade secrets to make and sell Devices/Leads in exchange for Medtronic-P.R.'s agreement to pay a royalty based on its net sales to Med USA. (Op/Add35-37; App38-55, 284.) The royalty rates were 29% for Devices and 15% for Leads.[7] (App41, 50.)

This appeal concerns the last agreement (Intercompany-Licenses).

During 2005-2006, Medtronic was the market leader regarding the Devices/Leads, and its operating profit margins for those products were extraordinary and "far outside the norm."[8] (Op/Add136; App817-818, 868-870, 1070.) Medtronic's extraordinary profitability was due in large part to its intangibles. (App366, 855, 861-867.)

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[7] These rates are wholesale rates (*i.e.*, rates that apply to intercompany sales between Medtronic-P.R. and Med USA). If converted to retail rates (*i.e.*, rates that apply to Medtronic's third-party sales at higher retail prices), the rates for Devices and Leads would be 20% and 10% respectively, based on Medtronic's conversion formula. (App254.)

[8] During 2005-2006, the operating profit margins on Leads (*i.e.*, profit divided by revenue) were slightly higher than those on Devices. (App743-744, 746-747.)

The profit generated by the Devices/Leads was allocated among Medtronic, Med USA, and Medtronic-P.R. through Medtronic's pricing of its intercompany agreements. (App839.) Pursuant to those agreements, Medtronic allocated over 65% of the profit to Medtronic-P.R. for its final-product manufacturing and the remainder to Medtronic's U.S. operations for all of the other functions. (App843.) In particular, Medtronic allocated 4% of the profit to its U.S. component-manufacturing operations (App424, 1000 n.27), even though Medtronic's U.S. and P.R. manufacturing operations engaged in similar activities and incurred similar costs (App842).

F. Audit of Medtronic's transfer pricing

While auditing Medtronic's consolidated U.S. tax return for 2002, the IRS questioned the pricing of the royalty rates paid by Medtronic-P.R. on the Intercompany-Licenses, determining that too much profit from the Devices/Leads was being shifted to Medtronic-P.R. and thus avoiding U.S. taxation. (Op/Add65-66.) The IRS's industry economist (Goodman) concluded that the transfer-pricing method employed by Medtronic (the CUT method, described above) was not the best method for the highly profitable intangibles licensed to Medtronic-P.R.

(Op/Add66.) He employed the residual profit-split method set out in § 1.482-6, and concluded that, based on the relative economic contributions of Medtronic's U.S. and Puerto Rican operations, 90% of the profits should be allocated to the U.S. operations and 10% to Medtronic-P.R. (App561-563, 674.) In response to Goodman's report, Medtronic offered to adjust its original CUT method and increase its royalty rates to an amount that would allocate more profit to its U.S. operations. (App565-566.)

To resolve the audit, the parties entered into a Memorandum of Understanding (MOU) whereby Medtronic-P.R. would pay royalty rates of 44% for Devices and 26% for Leads, subject to profit adjustments. (Op/Add66-67; App569-570.) Neither the IRS nor Medtronic considered the royalty rates in the MOU to be an arm's-length price, only a compromise to resolve the audit. (App559, 570-571.)

Pursuant to that compromise, the IRS agreed to respect the MOU's royalty rates in future years as long as there were no significant changes in any underlying facts. (Op/Add67.) When reviewing Medtronic's 2005-2006 tax returns, however, the IRS determined that Medtronic had violated the MOU, failing to report over $450 million in

royalty income during those years. (Op/Add70; App560.) The parties could not reach an agreement as to how the MOU should apply, and, accordingly, the IRS audited Medtronic's transfer pricing for 2005-2006. (App572-574.)

During the 2005-2006 audit, the IRS determined that the CPM was the best method for determining an arm's-length price for Medtronic's intercompany agreements. (Op/Add70.) Applying the CPM, the IRS further determined that the royalty rates that Medtronic-P.R. paid for the intangibles under the Intercompany-Licenses — and thus Medtronic's U.S. income — were too low, resulting in tax deficiencies for 2005-2006. (Op/Add70-71.) Medtronic contested those determinations and claimed an overpayment based on its original royalty rates in the Intercompany-Licenses. (Op/Add72-73.)

G. Tax Court proceedings

During the Tax Court proceedings, the parties disputed whether the CPM or the CUT method was the best method for determining an arm's-length royalty rate for the Intercompany-Licenses.

1. The Commissioner's transfer-pricing method (CPM)

The Commissioner argued that the CPM is the best method for determining an arm's-length price for the Intercompany-Licenses. (Op/Add88-89.) Under the CPM, an arm's-length result is determined by computing the profits that would have been earned by the "tested party" if its profitability were the same as that of uncontrolled comparable companies performing similar activities under similar circumstances. (App383-384, 1071-1072.) To apply that method, the Commissioner's expert (Heimert) selected Medtronic-P.R. as the tested party because it performed less complex functions than Medtronic. (*Id.*)

The first step under the CPM is to select companies that are comparable to the tested party, focusing on the assets utilized and the risks incurred. § 1.482-5(c)(2)(ii). Comparability of product and function is less important under the CPM than under other transfer-pricing methods. § 1.482-5(c)(2)(ii)&(iii). Heimert selected companies that devoted most of their resources to manufacturing implantable or invasive medical products, were responsible for product quality, and faced similar risks that Medtronic-P.R. faced, including product-liability

risk. (App417-418, 441-449, 459-472, 1081.) All except one were, like Medtronic-P.R., subject to FDA regulation. (App74-252, 417-418.)

The second step under the CPM is to select a profit-level indicator and apply it to the financial information of the comparable companies to determine their profitability. The regulations provide for several such indicators, including the return-on-operating-assets ratio. § 1.482-5(b)(4)(i). That indicator is most reliably applied when a company's operating assets play an important role in its ability to generate profits. *Id*. Because manufacturers like Medtronic-P.R. depend on their operating assets to generate profits, Heimert selected the return-on-operating-assets as the profit-level indicator. (App288-289.)

Applying the return-on-operating-assets ratio to the financial information of the selected companies and to Medtronic-P.R.'s financial information, Heimert computed a range of returns earned by the comparable companies and compared it to the returns earned by Medtronic-P.R.[9] (Op/Add94-95; App288-293, 420-423.) He determined

[9] Pursuant to § 1.482-1(e)(2)(iii)(B)&(C), Heimert used a statistical method that established a range of returns from multiple comparables and eliminated the outliers (referred to as an interquartile range), which minimized the impact of any differences between the comparables and Medtronic-P.R. (App1073-1074.)

that, in 2005, the comparable companies had a median return of 28.1% on their assets compared to Medtronic-P.R.'s 210.7% return on its assets, and that, in 2006, the comparables had a median return of 26.0% on their assets compared to Medtronic-P.R.'s 300.2% return on its assets. (App421-422.)

Given the vast disparity between the return to Medtronic-P.R. and the median return to the comparables, even though the companies utilized similar assets and faced similar risks, Heimert concluded that the profit allocated to Medtronic-P.R. was well above the arm's-length range. (App422-424, 1073-1074.) Based on his CPM analysis, Heimert determined that if Medtronic and Medtronic-P.R. had been acting at arm's length, rather than as related parties that could artificially set their intercompany prices, 8.1% and 5.6% of the operating profit for 2005 and 2006, respectively, would have been allocated to Medtronic-P.R. for its manufacturing function and the remaining profit to Medtronic's U.S. operations for its research and development, clinical and regulatory, component manufacturing, marketing, sales, and distribution functions. (Op/Add95-96; App424.) Heimert calculated that the resulting combined retail royalty rate paid for the

Intercompany-Licenses and the trademark license should be 49.4% for 2005 and 58.9% for 2006. (Op/Add119; App425.)

2. Medtronic's transfer-pricing method (CUT)

Medtronic argued that the CUT method was the best method for determining an arm's-length price for the Intercompany-Licenses. (Op/Add72-73.) To apply that method, its expert (Berneman) identified several transactions that involved a licensing of intangibles and argued that, of those transactions, the "best comparable" was a transaction between Medtronic and one of its competitors, Siemens Pacesetter (the Pacesetter agreement). (App575-576.) The Pacesetter agreement was a cross-license that Medtronic entered into with Pacesetter in 1992 in order to settle several pending lawsuits involving patent, antitrust, and employment issues. (Op/Add56-59; App56-73, 688-741, 1055-1057, 1061-1062.) To end the litigation, the parties entered into an agreement whereby Medtronic granted Pacesetter a "non-exclusive" license to use its patents for cardiac devices and leads in exchange for Pacesetter granting Medtronic a similar license regarding Pacesetter's patents. (App692.) Pacesetter also agreed to pay Medtronic $75 million plus a 7% royalty on future sales of devices and leads covered by

Medtronic's cardiac patents. (Op/Add58, 121; App699-700.) The cross-license involved only patents and specifically excluded all other intangibles. (App693-694, 1064-1065.) The initial term of the agreement was for 10 years, but was (pursuant to the original agreement) extended through 2005 after Pacesetter was acquired by another company. (Op/Add121.)

Berneman acknowledged that the Intercompany-Licenses granted exclusive rights and included improvements, whereas the Pacesetter agreement did not. (Op/Add122-124.) He nevertheless concluded that the agreement was a CUT, and adjusted the 7% retail royalty rate to 17% to account for exclusivity and improvements. (Op/Add123-124, 135.) Berneman did not, however, make any additional adjustments to account for the other differences identified by the Commissioner, including that the Pacesetter agreement (i) was part of a litigation settlement, (ii) included a $75 million lump-sum payment and a cross-license as consideration, (iii) included only patents and not other intangibles, (iv) required Pacesetter to engage in functions different from those engaged in by Medtronic-P.R., and (v) had far different profit potential than the Intercompany-Licenses. *See* App1088-1095

(Commissioner's listing of differences that would necessitate adjustments to the Pacesetter royalty rate). Treating the Pacesetter agreement (as adjusted) as a CUT, Berneman concluded that the royalties charged in the Intercompany-Licenses were consistent with arm's-length behavior. (Op/Add125.)

3. Tax Court opinion

The Tax Court determined that neither party's transfer-pricing analysis was reasonable. (Op/Add130-131.) The court first addressed the Commissioner's CPM analysis. The court rejected that analysis because (in the court's view) it (i) downplayed Medtronic-P.R.'s role in implementing Medtronic's quality standards, (ii) relied on medical-device manufacturers that performed more functions than Medtronic-P.R. and made different products, (iii) ignored the value of the intangibles licensed to Medtronic-P.R., and (iv) allocated too little profit to Medtronic-P.R. (Op/Add106-117.)

The Tax Court next addressed Medtronic's CUT analysis. The court rejected that analysis, finding it "unconvincing and vague" with insufficient adjustments for the differences between the Pacesetter agreement — Medtronic's "best comparable transaction" (Op/Add122) —

and the Intercompany-Licenses. (Op/Add126-128.) In particular, the court faulted Berneman for failing to "make upward adjustments" to the Pacesetter royalty "to account for lump-sum payments" (Op/Add126) and for "unacceptably lack[ing] an examination of the profit potential of his comparable transactions," as required by the regulations (Op/Add129). Given those flaws, the court concluded that the royalty rates proposed by Medtronic were not arm's length. (Op/Add129.)

Having rejected the transfer-pricing analysis of both parties, the Tax Court nevertheless concluded that the CUT method was the best method and that the "Pacesetter agreement is an appropriate CUT because it involved some of the same intangibles and had comparable circumstances." (Op/Add133, 138.) The court did not examine and compare the agreements' profitability before reaching that conclusion. (Op/Add135-137.) The court increased Berneman's adjusted royalty rate of 17% to 30% to account for Medtronic-P.R.'s access to Medtronic's know-how (7%), profit-potential differences between the Pacesetter agreement and the Intercompany-Licenses (3.5%), and product differences (2.5%). (*Id.*) The court did not make an upward adjustment

to account for the $75 million lump-sum payment or cross-license in the Pacesetter agreement. (*Id.*)

The Tax Court then converted its adjusted 30% retail rate to a 44% wholesale rate. (Op/Add137.) Although the Pacesetter agreement applied a uniform rate to both Devices and Leads, the court created a separate rate for Leads by cutting the 44% royalty in half to 22%. (Op/Add138.) The court attributed the 22% rate reduction to profit potential, asserting that the "device operations were substantially more profitable than the leads operations." (*Id.*)

As revised by the Tax Court, the royalty rates in the Intercompany-Licenses resulted in almost 50% of the profit from the Devices/Leads being allocated to Medtronic-P.R., with the rest allocated to Medtronic's U.S. operations.[10]

[10] For 2005, the Tax Court's royalty rates allocate 44% of the profit to Medtronic-P.R. (*i.e.*, Medtronic-P.R. was allocated $598 million of the $1.366 billion operating profit generated by Medtronic's Devices/Leads business). (App546-547, 598.) For 2006, Medtronic-P.R. was allocated 47% of the profit (*i.e.*, Medtronic-P.R. was allocated $925 million of the $1.968 billion operating profit generated by Medtronic's Devices/Leads business). (*Id.*)

SUMMARY OF ARGUMENT

This case involves a multinational company (Medtronic) that allocated a substantial amount of its income from its U.S. operations to its Puerto Rican operations (Medtronic-P.R.) in a manner that did not clearly reflect its true income, by charging an artificially low royalty rate for the extraordinarily profitable intangibles that it licensed to Medtronic-P.R. Medtronic-P.R. does the finished-product manufacturing of Devices/Leads for Medtronic to sell to U.S. customers. The low royalty resulted in over 60% of the profit from Medtronic's Devices/Leads business being allocated to Medtronic-P.R., even though it primarily performed the finished-product manufacturing and contributed only 11% of the costs to that business. Medtronic's U.S. operations performed all the other functions required to generate that profit, including research and development, clinical and regulatory work, component manufacturing, marketing, sales and distribution. The Tax Court rejected both parties' transfer-pricing analyses, and adopted a royalty rate (based on the Pacesetter agreement) that resulted in almost 50% of the profit being allocated to Medtronic-P.R.

1. The Tax Court's transfer-pricing analysis is wrong as a matter of law. It treated the Pacesetter royalty rate as a comparable price for Medtronic's Intercompany-Licenses without first applying Treasury regulations' strict requirements for evaluating whether an uncontrolled transaction like the Pacesetter agreement qualifies as a comparable uncontrolled transaction (CUT). The Pacesetter agreement does not qualify under the regulations because it (i) was a litigation settlement rather than a license entered into in the ordinary course of business, (ii) involved contractual terms (such as a large upfront payment and a cross-license) that were absent in the Intercompany-Licenses, (iii) covered only patents for cardiac products whereas the Intercompany-Licenses covered the full spectrum of technical intangibles, including regulatory approvals, for both cardiac and neurological products, (iv) required Pacesetter to perform far more functions than was required of Medtronic-P.R., and (v) had far less profit potential. The analysis required by the regulations, ignored by the Tax Court, demonstrates that the Pacesetter agreement cannot be utilized to price the Intercompany-Licenses.

2. The Tax Court's rejection of the Commissioner's transfer-pricing method is also wrong as a matter of law. The court's analysis cannot be squared with the relevant regulations or the record evidence. In particular, the court failed to apply the regulatory rules that were designed to facilitate the Commissioner's profit-based approach for situations where (as here) there is no comparable uncontrolled transaction. The Tax Court's decision should be reversed and the case remanded so that the court can correct its legal errors and reevaluate whether the Commissioner's method is the best method for determining an arm's-length price for Medtronic's intangibles.

3. Alternatively, the case should be remanded to the Tax Court to correct its adjustments to the Pacesetter royalty rate. In this regard, the court faulted Medtronic's expert for failing to take the Pacesetter agreement's $75 million lump-sum payment into account, and for failing to examine the agreement's profit potential as compared to that of the Intercompany-Licenses, but then made the same errors when calculating the royalty rate for the Intercompany-Licenses. In addition, the court adopted different royalty rates for Devices and Leads even though the Pacesetter agreement upon which the court relied provided

a uniform rate for those products. That error, too, should be corrected on remand, if this Court determines that the Pacesetter agreement may be treated as a comparable uncontrolled transaction.

ARGUMENT

The Tax Court erred in its determination of arm's-length royalty rates for the intangible assets licensed by Medtronic to its controlled foreign subsidiary, Medtronic-P.R.

Standard of review

The Tax Court's findings of fact are reviewed for clear error and its legal conclusions and mixed questions of law and fact are reviewed *de novo*. *Black Hills Corp. v. Commissioner*, 73 F.3d 799, 804 (8th Cir. 1996). When reviewing an allocation of income under I.R.C. § 482, courts "focus on the reasonableness of the result, not the details" of the "methodology" employed. *E.I. Du Pont De Nemours & Co. v. United States*, 608 F.2d 445, 454 (Ct. Cl. 1979).

A. Introduction

In 1986, Congress amended Section 482 to require that consideration for intangible property transferred between related parties be "commensurate with the income attributable to the intangible." I.R.C. § 482. Through that amendment, Congress sought

to remedy the "recurrent problem" of parties pricing certain "high value" intangibles transferred to "low tax jurisdiction[s]" based on uncontrolled transactions that were not in fact "comparable" to controlled transactions. H.R. Rep. No. 99-426, at 423-426. Congress directed "that the division of income between related parties reasonably reflect the relative economic activity undertaken by each." H.R. Rep. No. 99-841, at II-637. Treasury later implemented that mandate by tightening the standards for utilizing uncontrolled transactions to determine arm's-length pricing and by providing alternative profit-based methodologies that could be used to ensure that income allocations related to intangibles are commensurate with the parties' economic contributions. §§ 1.482-1, 1.482-4, and 1.482-5.

As demonstrated below, the Tax Court's reliance on the Pacesetter agreement as a comparable transaction under the CUT method, and its rejection of the Commissioner's CPM analysis, conflicts with Treasury's 1994 regulations and thwarts Congressional intent. The court treated the Pacesetter agreement as a comparable uncontrolled transaction without first applying the strict requirements under the CUT method. *See*, below, § B. And it rejected the Commissioner's CPM analysis

without first applying the regulations applicable to that method. *See*, below, § C.

Moreover, the result reached by the Tax Court is unreasonable and does not require Medtronic-P.R. to pay a royalty that is commensurate with the income attributable to the intangibles licensed by Medtronic, as required by I.R.C. § 482 and § 1.482-4(a). Splitting the income related to an intangible "'according to relative economic contributions is consistent with what unrelated parties do'" and implements the "'commensurate with income standard'" applicable to transfers of intangibles. (Op/Add84 (quoting Treasury report).) Although the Tax Court recognized this critical principle, it failed to apply it here by testing the reasonableness of the results of its transfer-pricing analysis against the objective measures of the parties' economic contributions. Instead, the court allocated almost 50% of the profit from the Devices/Leads to Medtronic-P.R., *see*, above, n.10, even though the court found that Medtronic-P.R. "did not perform" any of the "sales functions, research and development functions, and clinical functions" (Op/Add110) that were critical to generating that profit. Rather, Medtronic-P.R. primarily performed final-product manufacturing,

which — while important — represented only 11% of the economic costs related to the Devices/Leads. (App841-842.)

The case should be remanded so that the Tax Court can correct its legal errors, reevaluate the best method for pricing the Intercompany-Licenses, and determine an arm's-length royalty rate that accurately reflects Medtronic-P.R.'s economic contributions. Alternatively, the case should be remanded so that the Tax Court can correct the errors made in its Pacesetter royalty-rate adjustments. *See*, below, § D.

B. The Tax Court failed to apply the regulatory standards to the Pacesetter agreement and therefore erred as a matter of law in adopting it as a comparable transaction under the CUT method

The CUT method "evaluates whether the amount charged for a controlled transfer of intangible property was arm's length by reference to the amount charged in a comparable uncontrolled transaction." § 1.482-4(c)(1). To be "comparable," the transaction must satisfy the exacting standards set out in the 1994 regulations. § 1.482-4(c)(2)(iii). The uncontrolled transaction must involve "comparable intangible property" used in connection with "similar products" and arise under "comparable circumstances" as the controlled transaction at issue.

§ 1.482-4(c)(2)(iii). To be comparable, the intangibles "must" (among other things) have "similar profit potential" and "contractual terms." § 1.482-4(c)(2)(iii)(A), (B)(1)(ii). "[P]articularly relevant" under the CUT method is whether the "functions" performed by the transferees in the controlled and uncontrolled transactions are comparable. § 1.482-4(c)(2)(iii)(B)(2)(viii). Transactions that "are not made in the ordinary course of business" generally cannot be considered a CUT. § 1.482-1(d)(4)(iii). Although "adjustments [to an uncontrolled price] for differences" between the controlled and uncontrolled transaction are permitted, a court must consider whether the "number, magnitude, and reliability of those adjustments [affects] the reliability" of the results so as to preclude application of the CUT method. § 1.482-1(c)(2)(i).

As demonstrated below, the Tax Court failed to apply these regulatory requirements to the Pacesetter agreement. That agreement is not a comparable uncontrolled transaction because it (i) was not made in the ordinary course of business but was instead the product of a 1992 litigation settlement between Medtronic and Pacesetter; (ii) had vastly different contractual terms, including the use of an advance payment and a cross-license as part of the consideration for the

licensing of Medtronic's patents; (iii) did not involve "similar" intangibles because it covered only patents for cardiac products, whereas the Intercompany-Licenses provided all the intangibles required to manufacture and sell both cardiac and neurological products, including regulatory approvals; (iv) required Pacesetter to engage in far broader functions than was required of Medtronic-P.R. under the Intercompany-Licenses; and (v) had far less profit potential than the Intercompany-Licenses. Any one of these reasons casts serious doubt as to whether the Pacesetter agreement is a CUT, and, taken together, these reasons preclude the Pacesetter agreement from being treated as a CUT as a matter of law.

Even before Treasury tightened up the regulatory requirements for using comparable transactions to value intangible transfers in 1994, courts applying the earlier 1968 transfer-pricing regulations routinely rejected purportedly comparable transactions that shared some of the same differentiating attributes of the Pacesetter agreement. *E.g.*, *Podd v. Commissioner*, 1998 WL 345513, at *15 (T.Ct. 1998) (holding that "[l]icense fees negotiated in settlement of litigation" did not occur under "the same or similar circumstances" and therefore was not a comparable

transaction); *Seagate Tech., Inc. v. Commissioner*, 102 T.C. 149, 278-280 (1994) (holding that agreements that "involved different technology, required advance payments, provided a cross-license, granted exclusive rights, or contained geographic limitations" were not comparable transactions because they did not involve "similar intangible property" transferred under "similar circumstances"); *G.D. Searle & Co. v. Commissioner*, 88 T.C. 252, 374-375 (1987) (holding that intangibles that include "regulatory approvals" are "significantly more valuable than," and therefore not "comparable" to, intangibles without regulatory approvals). Given that the 1994 regulations have only tightened the requirements for CUTs, the Tax Court's failure to act in accord with this precedent is reversible error.

1. The Tax Court failed to account for the fact that the Pacesetter agreement was a litigation settlement

A transaction cannot be treated as a CUT unless it arose under "circumstances" comparable to the transaction at issue. § 1.482-4(c)(2)(iii)(B)(2). Moreover, transactions that "are not made in the ordinary course of business" generally are "not accepted as comparables." § 1.482-1(d)(4)(iii)(A)(1). The Pacesetter agreement was

not an ordinary business license but was instead the result of Medtronic's settling multiple lawsuits with one of its competitors. (Op/Add56-57; App56-73, 688-713, 925, 1055-1058, 1064-1066.)

The Tax Court failed to apply § 1.482-1(d)(4)(iii)(A)(1) or explain how a litigation settlement could be considered to have arisen in circumstances similar to the Intercompany-Licenses. Although the court "note[d] that the Pacesetter agreement came about because of litigation" (Op/Add128), it failed to consider the legal impact of that observation. It did not — and could not — find that the Pacesetter agreement was made in the "ordinary course of business." § 1.482-1(d)(4)(iii)(A)(1). Instead, it summarily concluded that the Pacesetter agreement and Intercompany-Licenses "had comparable circumstances" (Op/Add133), but failed to explain how a litigation settlement could be comparable to Medtronic's manufacturing arrangement with its Puerto Rican affiliate. Indeed, the Pacesetter agreement itself spelled out that it was not an ordinary business license but was instead designed to "reduc[e] the likelihood and expenses of future patent infringement Litigation between Medtronic and Siemens [Pacesetter] with respect to Cardiac Stimulation Devices." (App688.)

In a prior case, the Tax Court held that a license "granted in settlement of litigation" did not occur under "similar circumstances" to the controlled transaction at issue. *Podd*, 1998 WL 345513, at *15. As the court explained, license fees negotiated in settlement of litigation "may not be indicative of a true arm's-length royalty because of the incentive to avoid high litigation costs." *Id.*; *cf. Rude v. Westcott*, 130 U.S. 152, 164 (1889) ("It is clear that a payment of any sum in settlement of a claim for an alleged infringement cannot be taken as a standard to measure the value of the improvements patented [because] [m]any considerations other than the value of the improvements patented may induce the payment in such cases."). Given the stricter comparability requirements for the CUT method that apply in this case, as compared to the pre-1994 regulations applied in *Podd*, the Tax Court should have reached the same conclusion here.

2. The Tax Court failed to account for the $75 million lump-sum payment, a significant portion of the Pacesetter agreement's consideration

Evaluating whether transactions are comparable "requires a comparison of the significant contractual terms that could affect the results of the two transactions," including the "form of consideration

charged or paid." § 1.482-1(d)(3)(ii)(A)(1); *see* § 1.482-4(c)(2)(iii)(A). In the Pacesetter agreement, Medtronic obtained three forms of consideration for licensing its patents: a 7% royalty, a $75 million lump-sum payment, and a cross-license that allowed Medtronic to use Pacesetter's patents. (Op/Add58; App692, 699-700.) In contrast, the consideration for the Intercompany-Licenses was only a royalty and did not include a lump-sum payment or a cross-license. (App38-55.) Moreover, the upfront $75 million payment was a major component of the value of the Pacesetter agreement, given that Medtronic expected to receive $200-300 million from Pacesetter over the life of the agreement. (Op/Add57.)

The Tax Court failed to apply § 1.482-1(d)(3)(ii)(A)(1) and consider whether the Pacesetter lump-sum payment — a significant contractual difference in the form of the consideration paid — precluded the Pacesetter agreement from being a CUT.[11] When faced with a similar royalty arrangement, whereby a licensee paid both a royalty and a lump-sum "fee up front," the Tax Court previously concluded that such

[11] The Tax Court's failure to account for the cross-license is addressed in the following section.

a hybrid pay structure precluded an uncontrolled license from being comparable to the controlled license at issue. *Bausch & Lomb Inc. v. Commissioner*, 92 T.C. 525, 600 (1989) (observing that a "licensee [required to make an upfront payment] would demand a lower overall royalty rate than he would be willing to pay under normal circumstances"), *aff'd*, 933 F.2d 1084 (2d Cir. 1991); *see Seagate*, 102 T.C. at 280 (holding that agreements "requir[ing] advance payments" were not comparable to one without that feature). Given the stricter comparability requirements for the CUT method that apply in this case, as compared to *Bausch* and *Seagate*, which were decided under the pre-1994 regulations, the Tax Court should have reached the same conclusion here.[12]

3. The Tax Court failed to account for the fact that the Pacesetter agreement was a cross-license

Evaluating whether transactions are comparable not only requires a comparison of their "contractual terms," § 1.482-4(c)(2)(iii)(A), but it

[12] Alternatively, if this Court were to determine that the Tax Court did not err in treating the Pacesetter agreement as a CUT, the case should be remanded with instructions that the court account for the lump-sum payment in its adjustments to the Pacesetter royalty rate, as discussed below in § D.

also requires consideration of the "existence and extent of any collateral transactions . . . between the transferee and transferor," § 1.482-4(c)(2)(iii)(B)(2)(vii). The Pacesetter agreement involved a collateral transaction — the cross-license whereby Pacesetter licensed its cardiac patents to Medtronic. (App692, 874, 924-925.)

The Tax Court failed to apply § 1.482-4(c)(2)(iii)(B)(2)(vii) and consider whether the Pacesetter cross-license was a collateral transaction that precluded the Pacesetter agreement from being a CUT. In a prior case, the Tax Court held that a transfer that included a "cross-license" was not comparable to a transfer that did not. *Seagate*, 102 T.C. at 280. There is no reason to reach a different conclusion here. As one of the Commissioner's experts explained, "you can't compare a cross-license with a license that doesn't have a cross-payment going the other way." (App1070.) The royalty in a cross-license is lower than, and therefore not comparable to, a royalty in a one-way license because the former nets one royalty against another. (App874.) For example, a cross-license with a 10% royalty could result from a license in one direction worth 40% netted against a license in the other worth 30%.

The 10% netted figure would not be comparable to a single, non-netted royalty. (App874 n.90.)

Although the Tax Court observed that "Medtronic US attributed no value to the Pacesetter patents it received as part of the cross-license" (Op/Add58) because Medtronic was of the view that its patents did not infringe Pacesetter's patents (App1054, 1064), the court did not actually determine the value of the Pacesetter patents. Nor could it, given that Medtronic provided no evidence of their value. Moreover, Medtronic acknowledged that the cross-license did provide it "some value" in removing existing and future patent litigation, particularly given that it was a "small company" at the time and it was "nearly crippling to have that kind of litigation." (App1064.) The Tax Court should have rejected the Pacesetter agreement as a comparable transaction because the court could only "speculate on the relative value of the . . . cross-licensing agreements."[13] *Seagate*, 102 T.C. at 280.

[13] Alternatively, the cross-license requires an upward adjustment to the Tax Court's Pacesetter-based royalty rate. *See*, below, § D.

4. The Tax Court's conclusion that the intangibles licensed to Pacesetter and Medtronic-P.R. were the "same" conflicts with its findings demonstrating they were different

The CUT method cannot be applied unless the controlled and uncontrolled transactions involve "comparable intangible property." § 1.482-4(c)(2)(iii)(A). *See Sundstrand Corp. v. Commissioner*, 96 T.C. 226, 385-387 (1991) (holding that an uncontrolled license did not involve "similar intangible property" where the controlled license "applies to a broader range of property" than the uncontrolled license, including "future technology and know-how" which were "invaluable"); *Searle*, 88 T.C. at 374-375 (holding that intangibles that include "regulatory approvals" were "significantly more valuable" than, and therefore not "comparable" to, intangibles without regulatory approvals). The Pacesetter agreement and the Intercompany-Licenses do not involve comparable intangible property because they licensed different intangibles. The Tax Court's contrary conclusion that the agreements involve the "same intangibles" (at least as regards to Medtronic's cardiac devices) (Op/Add133) conflicts with the language of the agreements and the court's own findings.

As the Pacesetter agreement and the Intercompany-Licenses make clear, the intangibles licensed to Pacesetter were only certain patents for cardiac products in existence in 1992, whereas the intangibles licensed to Medtronic-P.R. over a decade later (i) related to both cardiac and neurological products, and (ii) included far more than patents. (App38-55, 688-713.) The Pacesetter agreement expressly was limited to "Patents" and specifically excluded all other intangibles, including "any technical know-how or design information, manufacturing, marketing, and/or processing information or know-how, designs, drawings, specifications, software source code or other documents directly or indirectly pertinent to the use of the Licensed Patents." (App693-694.) The Intercompany-Licenses, in contrast, included *all* of the intangibles excluded by the Pacesetter agreement. (App38-55.)

Consistent with those agreements, the Tax Court found that the Intercompany-Licenses included the following technical information and legal rights developed and owned by Medtronic:

- inventions,
- secret processes,

- technical design expertise,
- patents,
- trade secrets,
- know-how,
- copyrights,
- product regulatory approvals, and
- future "improvements" regarding those intangibles.

(Op/Add35-36.) The court further found that the Pacesetter agreement licensed only "patent portfolios." (Op/Add121.)

Those findings, however, were ignored by the Tax Court in its analysis of whether the Pacesetter agreement could qualify as a CUT. In this regard, the court determined that the Pacesetter agreement could qualify as a CUT because (according to the court) the only difference between the intangibles licensed to Pacesetter and those licensed to Medtronic-P.R. is that Pacesetter's license "included only CRDM [*i.e.*, cardiac] products" whereas the Intercompany-Licenses included both cardiac and neurological products. (Op/Add133.) That is incorrect; the difference between the two licenses is far more extensive. (App924-926.) Unlike the "full suite of intangibles" provided in the

Intercompany-Licenses, the Pacesetter agreement did not provide the licensee any ability to exploit the licensed intangibles, other than the security of not being sued for patent infringement. (App1075-1077.)

The Tax Court did not cite — and our research has not uncovered — a single case treating a patent license as comparable to a license providing all the intangibles (including regulatory approvals) required to manufacture and sell a product. As in *Searle* and *Sundstrand*, the stark difference in the type of intangibles licensed in the Pacesetter agreement and the Intercompany-Licenses precludes the Pacesetter agreement from being a CUT.

5. The Tax Court failed to analyze whether Pacesetter and Medtronic-P.R. engaged in comparable functions

To determine whether an uncontrolled transaction was entered into under circumstances comparable to a controlled transaction, it is "particularly relevant" under the CUT method whether the "functions" performed by the transferees of the intangibles are similar. § 1.482-4(c)(2)(iii)(B)(2)(viii). The Tax Court, however, failed to apply that regulation in determining that the Pacesetter agreement "is an appropriate CUT" without comparing the functions performed by

Pacesetter and Medtronic-P.R. to see if they were sufficiently similar. (Op/Add133.)

The functions performed by Pacesetter and Medtronic-P.R. are not comparable. (App767-769, 924.) Medtronic-P.R. performed only finished-product manufacturing and "did not perform," as the Tax Court found, any of the other functions required to produce Devices/Leads for sale, including "sales functions, research and development functions, and clinical functions." (Op/Add110.) Pacesetter, in contrast, performed all of those functions. (App767-769, 814-815, 1076-1077.) Given the limited nature of the intangibles licensed in the Pacesetter agreement, Pacesetter — unlike Medtronic-P.R. — had to (i) develop and use its own technical know-how, trade secrets, specifications, marketing information, and software and (ii) obtain its own regulatory approvals, which are costly and time-consuming. The Pacesetter agreement thus fails the functional-comparability factor under the CUT method.

6. The Tax Court failed to analyze whether the intangibles had similar profit potential

To be considered comparable under the CUT method, both intangibles must (among other things) "[h]ave similar profit potential."

§ 1.482-4(c)(2)(iii)(B)(1)(ii). The Tax Court acknowledged this regulatory requirement (Op/Add131-132) and criticized Medtronic's expert for "unacceptably lack[ing] an examination of the profit potential" of the Pacesetter agreement (Op/Add129). But, in adopting the Pacesetter agreement as a CUT, the court made the same error. The court did not examine and compare the profit potential of the Pacesetter agreement and the Intercompany-Licenses. The court simply skipped over this required analytical step and made an arbitrary adjustment to the Pacesetter royalty rate for profit potential (addressed below in § D).

If the Tax Court had analyzed the profit potential of the Pacesetter agreement and the Intercompany-Licenses — as the regulations expressly require — it would have concluded that there was no similarity between the two whatsoever. Although Medtronic's expert failed to analyze profit potential (as the court found (Op/Add135)), the Commissioner's experts did engage in the required analysis (which the court ignored). As the Commissioner's experts concluded, the vast difference in profit potential between the Pacesetter agreement and the Intercompany-Licenses precluded any use of the agreement as a CUT.

(App585-587, 817-818, 962-963.) In this regard, operating profit margins are the primary driver of royalty rates (App869), and Medtronic's margin was 52.6% whereas Pacesetter's was only 17.7%, as the Commissioner emphasized (App595).

7. The Tax Court failed to evaluate whether the number and extent of required adjustments precluded the Pacesetter agreement from being a reliable comparable

A transfer-pricing method cannot be used if the "number, magnitude, and reliability of [the] adjustments" necessitated by differences between the controlled and uncontrolled transactions undermine the result's reliability. § 1.482-1(c)(2)(i). Citing this regulation, the Commissioner argued that the Pacesetter agreement could not be utilized as a CUT because Berneman's proposed adjustment from 7% to 17% was too large to be reliable (over double the specified royalty rate), particularly given that he did not even include all the adjustments required by the differences between the Pacesetter agreement and the Intercompany-Licenses. (App1090.) The Tax Court, however, failed to apply this regulation. Instead, the court simply concluded "that appropriate adjustments should be made to [Medtronic's] CUT" (Op/Add132), and increased the Pacesetter retail

royalty from 7% to 30%, without regard to whether the extensive nature of the adjustments made the CUT method so unreliable as to preclude its use under § 1.482-1(c)(2)(i).

The Tax Court erred as a matter of law by failing to consider whether the magnitude and nature of its adjustments rendered the CUT method unreliable. Increasing the Pacesetter royalty from 7% to 30%[14] is an adjustment of over 400%. Moreover, if the Pacesetter agreement were to be used as a CUT, even further upward adjustments are required, as explained below in § D. As § 1.482-1(c)(2)(i) indicates, at some point, a purportedly comparable price ceases to be that under the weight of the required adjustments to that price, such that the final price becomes an engineered artifice wholly lacking in reliability. That point was reached — and exceeded — here.

8. The Tax Court failed to evaluate whether the results of its CUT method are reasonable

Although we have outlined the myriad legal errors in the Tax Court's CUT analysis, we do not mean to blur the forest by detailing the trees. In transfer pricing, as the Tax Court itself acknowledged, the

[14] 30% is the percentage applicable to retail sales, which the Tax Court converted to 44% for wholesale sales. (Op/Add137.)

"reasonableness of the result" is more important than the "details of the methodology employed." (Op/Add117-118.) Where the transfer involves intangibles, a result is not reasonable unless it is commensurate with the parties' economic contributions to the intangibles' income. I.R.C. § 482; § 1.482-4(a); H.R. Rep. No. 99-841, at II-637. The Tax Court purported to evaluate the reasonableness of the results of the Commissioner's transfer pricing (an error addressed below, § C.4), but made no attempt to evaluate the reasonableness of its own results. (Op/Add117-118.)

The unreasonableness of the Tax Court's transfer pricing is demonstrated by the profit allocation that results from the royalty rates adopted by the court. Those royalties result in an allocation of almost 50% of the profit from the Devices/Leads to Medtronic-P.R., *see*, above, n.10, even though it primarily performed only one major function and incurred only 11% of the total relevant costs (Op/Add110; App841-842). The exceptional profitability of the Devices/Leads was due, for the most part, to the economic contributions of Medtronic's U.S. operations. (App366, 372-374, 851-857.) Medtronic invested more money and time in research and development than any of its competitors to develop the

intangibles at issue, engaged in the necessary clinical trials, obtained the required regulatory approvals, and employed the executive management who developed the business and marketing strategies. (App327, 334-365, 372-374.) Medtronic-P.R.'s principal contribution to the Devices/Leads business was finished-product manufacturing (Op/Add110), while Medtronic and Med USA did everything else, including bearing almost 90% of the relevant costs (App1067-1068).[15]

This objective evidence demonstrates that the CUT method is unreliable because it allocates an unreasonable percentage of profit to Medtronic-P.R. that is not even remotely commensurate with its economic contributions. The Tax Court's use of the CUT method on the basis of the Pacesetter agreement, resulting in an unreasonable allocation of income to Medtronic-P.R., warrants reversal by this Court.

[15] In sharp contrast, the Tax Court's transfer pricing allocated only 4% of the profit to Medtronic's U.S. manufacturing divisions, even though their economic contributions to the Devices/Leads exceeded that of Medtronic-P.R. (App407, 424, 842, 1000 n.27), and they were responsible for developing the most sophisticated components in these complex medical devices (Op/Add17-20; App350-352).

C. The case should be remanded to the Tax Court to reevaluate whether the CPM is the best transfer-pricing method because the court's rejection of that method conflicts with the regulations

Given the magnitude of the flaws with the CUT method outlined above, the Tax Court's decision should be reversed and the case remanded with instructions that it reevaluate whether the CPM is the best method to determine an arm's-length price for the Intercompany-Licenses (with or without adjustments). § 1.482-1(c). As explained above, the CPM evaluates whether the price charged in a controlled transaction (*i.e.*, the royalty charged to Medtronic-P.R. for use of Medtronic's intangibles) is arm's length according to objective measures of profitability derived from uncontrolled companies that engage in similar business activities under similar circumstances. § 1.482-5.

The Commissioner's expert (Heimert) applied the CPM as provided for in § 1.482-5, and determined an arm's-length profit for Medtronic-P.R. consistent with the returns earned by comparable companies. To calculate that profit, Heimert identified 14 companies that manufactured implantable or invasive medical devices (or, in one instance, components for implantable medical devices), calculated their return on their assets (using the book value of those assets), produced

an interquartile range of results from those calculations, and then applied the median of that range to the book value of Medtronic-P.R.'s assets to determine the level of profits one would expect Medtronic-P.R. to obtain if it were an unrelated party transacting with Medtronic to manufacture its Devices/Leads. (App417-426, 1078.) As demonstrated below, the Tax Court's rationales for rejecting Heimert's analysis conflict with § 1.482-5 and the objective evidence in the record.

Before addressing those rationales, it bears noting that, in rejecting the Commissioner's CPM analysis, the Tax Court relied on Medtronic's expert, Pindyck, even though he was "critical" of the CPM as a transfer-pricing method. (Op/Add113.) His criticism was predicated on his view that the "CPM method" is "not based on economic principles, and thus yields results that cannot be relied upon." (App993.) The Treasury Department, however, disagrees, and has promulgated regulations establishing the CPM as a suitable transfer-pricing method. § 1.482-5. Indeed, Treasury has utilized that method in the vast majority of its Advance Pricing Agreements with taxpayers. (App1079-1080.) Although Medtronic's expert may question the wisdom of § 1.482-5, the Tax Court was required to apply it. Where (as here)

there is "no challenge to the validity of the [Section 482] regulations," a court must "apply them as they are, with fidelity to both their words and their spirit." *Du Pont*, 608 F.2d at 450. The court's failure to do so here is reversible error. On remand, the Tax Court should apply the regulations as written and reconsider the CPM, taking into account the analysis set out below.

1. Medtronic-P.R.'s role in implementing Medtronic's quality standards provides no basis for rejecting Heimert's CPM analysis because Heimert's comparables served similar roles

The Tax Court determined that the Commissioner's CPM analysis did not give appropriate weight to the role of Medtronic-P.R. because Medtronic-P.R. "did more than assemble components" and served an important "role in quality." (Op/Add117.) That criticism, however, ignores that the companies selected by Heimert in his CPM analysis also did more than assemble components and were responsible for the quality of their products. (Op/Add94, 110-111.)

All of Heimert's comparables (except one) were medical-device manufacturers that were — like Medtronic-P.R. — subject to FDA regulation, registration, and inspection, and all were concerned about product-liability risk, as their public filings with the SEC make clear.

(App74-252, 417-418, 441-449.) Moreover, all of Heimert's comparables were — like Medtronic-P.R. — "responsible for the quality of their products." (App417.)

The Tax Court did not — and could not — find that the medical-device manufacturers utilized by Heimert in his CPM analysis were less concerned about quality than Medtronic-P.R. Like Medtronic, their market position and revenue depended on "reliable product quality." (App113, 860-866.) Any defect in product quality would expose the manufacturer to product liability, a risk faced by each of Heimert's comparables. As one of those comparables explained in its SEC filing, "[p]roduct liability is a commercial risk for the industry." (App209.)

Thus, concern about product quality was not unique to Medtronic. (App851-852.) Rather, as Medtronic acknowledged in the Tax Court, "[p]roduct quality is the foundation upon which everything else rests in the implantable medical device industry." (App593.) By relying on the returns earned by other implantable or invasive medical-device manufacturers, which were all concerned with product quality, Heimert's CPM analysis properly accounted for the importance of quality in the production process. Accordingly, Medtronic-P.R.'s role in

product quality provides no basis for the Tax Court's rejection of Heimert's CPM analysis.

2. Heimert's selection of comparable companies is consistent with the regulations

The Tax Court further determined that Heimert's "comparable companies are not consistent with the regulations" because their "products" and "functions" were "different" than, and not the "same" as, those of Medtronic-P.R. (Op/Add109-111.) The regulations, however, do not require the comparables to be the "same" — only "sufficiently similar that it provides a reliable measure of an arm's length result." § 1.482-1(d)(2).

The regulations further emphasize that the general comparability factors set out in § 1.482-1 should be tailored to the specific transfer-pricing method at issue, and that when applying the CPM, certain comparability factors are less important. §§ 1.482-1(c)(2)(ii)(C), 1.482-1(d)(1), 1.482-5(c)(2)(ii)&(iii). The comparability factors cited by the Tax Court — related to the products and functions of Heimert's comparables — are less important under the CPM than under other transfer-pricing methods. § 1.482-5(c)(2)(ii)&(iii). As the regulations provide, "differences in product characteristics will ordinarily have a greater

effect" on transaction-based methods "than on a comparable profits method analysis." § 1.482-1(c)(2)(ii)(C); *accord* § 1.482-5(c)(2)(iii). Similarly, the "degree of functional comparability required to obtain a reliable result under the [CPM] . . . is generally less than that required under" other transfer-pricing methods. § 1.482-5(c)(2)(ii); *see* § 1.482-8, Ex. 6 (illustrating the lessened functional and product comparability requirements of the CPM). The comparability analysis under the CPM focuses instead on "resources employed and risks assumed." § 1.482-5(c)(2)(ii).

The regulations explain why product and function comparability is less important under the CPM than under other transfer-pricing methods, such as the CUT method where they are "particularly relevant." § 1.482-4(c)(2)(iii)(B)(2). Product similarity is less important under the CPM because the CPM determines an arm's-length price based on operating profits, and "operating profit usually is less sensitive than gross profit to product differences." § 1.482-5(c)(2)(iii). Similarly, functional comparability is less important under the CPM because "differences in functions performed often are reflected in operating expenses," so that companies "performing different functions may have

very different gross profit margins but earn similar levels of operating profit." § 1.482-5(c)(2)(ii).

The Tax Court ignored § 1.482-5(c)(2)(ii)&(iii) when evaluating Heimert's comparables under the CPM. That Heimert's comparables made different medical devices and performed additional functions, as compared to Medtronic-P.R., does not preclude use of the CPM. Indeed, if it did, the CPM for transfer pricing would be rendered largely meaningless. What is important under the CPM, and what the Tax Court failed to appreciate, is that Heimert's comparables manufactured medical devices that required "similar" resources and involved "similar" risks. (App446-447.)

The Tax Court also failed to recognize that functional differences are mitigated under the CPM by using an assets-based profit-level indicator. *See* § 1.482-5(b)(4)(ii). Heimert selected the return-on-operating-assets profit-level indicator precisely for this reason. (App289.) As Heimert explained, any non-manufacturing activities performed by the comparable companies (such as marketing or research and development) are not asset-intensive types of activities and

therefore should not materially affect the reliability of the CPM's results. (App289, 1082-1083.)

The Tax Court also ignored that differences in comparability are further mitigated by Heimert's use of an interquartile range of results provided for in the regulations. § 1.482-1(e)(2)(iii)(B)&(C). Pursuant to this statistical method, Heimert used a group of companies rather than relying on a single comparable (as the Tax Court did in applying the CUT method), eliminated outliers, and calculated an arm's-length range. (App420-422.) Using this range smooths out any differences between Medtronic-P.R. and any given comparable regarding a specific aspect, such as company size, because it accounts for the fact that some companies will be larger than Medtronic-P.R. and some will be smaller. The Tax Court failed to address the impact this approach had on the reliability of Heimert's results.

Moreover, the Tax Court's rejection of Heimert's comparables under the CPM is inconsistent with its acceptance of the Pacesetter agreement as a CUT. The court thus rejected Heimert's comparables because they involved products and functions different from those related to the Intercompany-Licenses, but, at the same time, accepted

the Pacesetter agreement even though it involved products and functions different from those related to the Intercompany-Licenses.[16] That the court treated the Pacesetter agreement as a CUT *despite* differences in product and function, but rejected the CPM *because* of differences in product and function, inverts the regulatory standards, given that the regulations expressly permit greater differences in product and function under the CPM than under the CUT. § 1.482-5(c)(2)(ii)&(iii).

Finally, the Tax Court's criticism that Heimert used the same comparables to determine the arm's-length profit attributable to both Medtronic's U.S. component manufacturing and Medtronic-P.R.'s final-product manufacturing (Op/Add112) cannot justify the court's rejection of Heimert's application of the CPM to Medtronic-P.R. In the court's view, a "components manufacturer has a role different from that of a final product manufacturer" (Op/Add112) and, therefore, the same

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[16] With regard to products, the Intercompany-Licenses covered neurological products, whereas the Pacesetter agreement did not. (Op/Add124-125.) And, with regard to functions, the Pacesetter agreement required Pacesetter to engage in numerous non-manufacturing functions, such as research and development, clinical, and sales, that the court found Medtronic-P.R. "did not perform." (Op/Add110; App767-769, 814-815.)

companies should not be used to determine arm's-length returns for both component and final-product manufacturers. Although we disagree with that premise (which finds no support in the regulation), it has no impact on the reliability of Heimert's analysis of Medtronic-P.R.'s profit. Medtronic-P.R. is a final-product manufacturer, just like all (but one) of Heimert's comparables. Therefore, even if Heimert's final-product manufacturers were inappropriate comparables to evaluate the profit of Medtronic's component manufacturing (an issue not in dispute), they were entirely appropriate to evaluate the profit of Medtronic-P.R.'s final-product manufacturing.

Accordingly, if this Court reverses the Tax Court's treatment of the Pacesetter agreement as a CUT, as it should, then, on remand, the Tax Court should be instructed to reevaluate Heimert's comparables under the standards provided in § 1.482-5(c)(2)(ii)&(iii), taking into account that differences between the comparables and Medtronic-P.R. are mitigated by the use of an assets-based profit-level indicator and an interquartile range of results. Moreover, if after applying the correct legal standard, the court were to conclude that any specific company did not employ similar resources or face similar risks, then the appropriate

solution would be to adjust Heimert's analysis by eliminating that particular company from his pool of comparables, not rejecting the CPM method altogether.

3. Heimert's use of the return-on-operating-assets as a profit-level indicator is consistent with the regulations

The Tax Court's criticism of Heimert's use of the return-on-operating-assets profit-level indicator also conflicts with the regulations. The court cited Pindyck's complaint that Heimert's return-on-operating-assets analysis did not provide a fair market valuation of Medtronic-P.R. as an "operation," but instead relied on Medtronic-P.R.'s book value. (Op/Add114; *see* App589-591.) Pindyck advocated for valuing Medtronic-P.R. by how much it would cost to replace its manufacturing operations, rather than its book value. (*Id.*) The regulations, however, do not require a replacement-value method and specifically allow the Commissioner to measure "[o]perating assets" by "their net book value" rather than "by their fair market value, provided that the same method is consistently applied to the tested party and the comparable parties." § 1.482-5(d)(6). Heimert consistently measured

the operating assets of both Medtronic-P.R. and the comparable companies by their book value. (App421, 459-472, 530-531.)

The Tax Court also concluded that Heimert's use of the return-on-operating-assets profit-level indicator was "misleading because it ignores the value of the licensed intangibles" that were "obtained" through the Intercompany-Licenses. (Op/Add114.) That conclusion, however, disregards the regulations. The regulations simply require consistent treatment of the operating assets of the tested party and the comparable companies, § 1.482-5(d)(6), and adjustments that improve reliability, § 1.482-5(c)(2)(iv). Heimert followed those requirements. His return-on-operating-assets computations for the comparable companies excluded any intangibles (owned or licensed) from the assets of the comparable companies. (App452-453.) Those computations are consistent with his exclusion of the value of the licensed intangibles from Medtronic-P.R.'s assets. Because Heimert's exclusion of intangibles was "consistently applied," § 1.482-5(d)(6), and increased the reliability of the results, it satisfies the regulations.

Moreover, Medtronic-P.R. did not "obtain" the intangibles through the Intercompany-Licenses, as the court incorrectly assumed

(Op/Add114). Rather, Medtronic-P.R. merely licensed the intangibles from Medtronic, the owner of the intangibles. (App43, 52, 336, 366.) Therefore, Heimert properly did not include Medtronic's intangibles in Medtronic-P.R.'s operating assets.

In rejecting Heimert's use of the return-on-operating-assets profit-level indicator (Op/Add112-114), the Tax Court failed to consider whether any other CPM profit-level indicator could be applied in this case. In particular, the court failed to address Heimert's alternative computation of the return-on-costs profit-level indicator and his calculations using that indicator for each of the comparable companies. (App459-473, 479-493, 1085-1086.) On remand, the court should be instructed to consider both profit-level indicators in its reevaluation of the CPM.

4. Measured against the objective evidence, Heimert's profit allocation is reasonable

Finally, the Tax Court rejected the CPM because (in its view) Heimert's allocation of 6-8% of the profit from the Devices/Leads to Medtronic-P.R. was "not reasonable." (Op/Add117-118.) The court, however, cited no support for that conclusory determination, stating only that "[i]t is difficult to place an exact value on what [Medtronic-

P.R.] contributed to the manufacturing of devices and leads, but it is certainly more than" the amount allocated by Heimert. (Op/Add117.)

The objective benchmarks in the record, however, support Heimert's allocation of 6-8% of the profit to Medtronic-P.R. For example, the arm's-length profit allocated to Medtronic's U.S. component-manufacturing operations under the Tax Court's decision was only 4%. (Op/Add75; App424, 1000 n.27.) That percentage is far more consistent with Heimert's allocation of profit to Medtronic-P.R. (6-8%) than with the court's allocation (44-47%). Although the court found that component manufacturing and finished-product manufacturing were not identical (Op/Add112), the court could not — and did not — find that they were so different as to justify allocating over 10 times as much profit to Medtronic-P.R. for its finished-product manufacturing as was allocated to Medtronic for its component manufacturing, particularly given that Medtronic spent more resources on its component manufacturing than Medtronic-P.R. spent on its finished-product manufacturing (App842).

The relative costs borne by Medtronic-P.R. and Medtronic's U.S. operations provides another objective benchmark that supports

Heimert's allocation. Medtronic-P.R. bore only 11% of the external costs related to Medtronic's Devices/Leads business. (App841-842.) Although profits and costs may not be strictly aligned in every case (as Medtronic's expert posited (App588)), the vast disparity between the profits allocated to Medtronic-P.R. (44-47%) and the costs borne by Medtronic-P.R. (11%) supports Heimert's profit allocation and illuminates the unreasonableness of the Tax Court's allocation. *See Du Pont*, 608 F.2d at 456 (relying on "two economic indices" of income-to-costs ratio and rates-of-return to test the reasonableness of the Commissioner's Section 482 reallocation).

Finally, the Goodman report cited by the Tax Court (Op/Add66) provides an objective benchmark that supports Heimert's allocation. The report concluded that, under the residual profit-split method set out in § 1.482-6, 90% of the profits should be allocated to Medtronic's U.S. operations and 10% to Medtronic-P.R. based on the relative economic contributions of Medtronic's U.S. and P.R. operations. (App562-563, 673-674.) This last objective benchmark is particularly pertinent, given that the reliability of a transfer-pricing method is confirmed when it produces results "that are consistent with the results

obtained from the appropriate application of another method." § 1.482-1(c)(2)(iii).

In rejecting Heimert's analysis as unreasonable, the Tax Court emphasized that Medtronic-P.R. manufactured Class III medical devices. (Op/Add117.) But the fact that the Devices/Leads were Class III products weighs in favor of allocating more, not less, in total profit to Medtronic. As the court found, Class III products are required to go through a lengthy and expensive preapproval process that can take 5-10 years to complete before the device can be sold in the United States. (Op/Add8-9.) And, as the court further found, Medtronic "bore the significant costs" related to that process. (Op/Add16.) Accordingly, because Medtronic — not Medtronic-P.R. — heavily invested in the "rigorous, costly, and time consuming" preapproval process required of Class III devices (Op/Add9), and licensed those regulatory approvals to Medtronic-P.R., the royalty rate should compensate Medtronic for the extensive research and development, clinical, and regulatory efforts required to allow a Class III device to be manufactured for sale in the first place.

In sum, the Tax Court's criticism of the Commissioner's CPM analysis cannot withstand scrutiny. On remand, the court should reevaluate whether the CPM is the best method for determining an arm's-length price for the Intercompany-Licenses. If, after correcting the errors in its CPM analysis, the court determines that the CPM is not the best method, it should then determine an arm's-length price based on the "record as a whole." *Bausch*, 92 T.C. at 597.

D. Alternatively, if the Pacesetter agreement is treated as a comparable uncontrolled transaction under the CUT method, the Tax Court on remand should be instructed to revise its adjustments to the Pacesetter royalty rate

For the reasons explained above in § B, we maintain that the Pacesetter agreement is not a comparable uncontrolled transaction and that the Tax Court's use of its royalty rate as a starting point for determining an arm's-length price for the Intercompany-Licenses was reversible error as it is contrary to the regulations, inconsistent with prior case law, and completely arbitrary. If, however, this Court were to disagree, it should nevertheless remand the case so that appropriate adjustments can be made to the Tax Court's Pacesetter-based royalty rate to (i) account for the Pacesetter agreement's $75 million lump-sum

payment and cross-license, (ii) provide a uniform royalty rate for Devices and Leads, and (iii) accurately account for the difference in profit potential between the agreements.

1. Adjustments based on corrected value of the Pacesetter agreement

The Tax Court's computation of arm's-length royalty rates for the Intercompany-Licenses was based on an inaccurate assessment of the Pacesetter agreement's initial "value." (Op/Add136.) The court assumed that value to be a 7% royalty, and then made several adjustments keyed to that number. (Op/Add134-137.) The actual value of the Pacesetter agreement, however, was much more than a 7% royalty, and included a $75 million lump-sum payment and a cross-license, as explained above in § B.2-3. The upfront $75 million payment in particular was a major component of the value of the Pacesetter agreement, given that Medtronic expected to receive $200-300 million over the life of the agreement. (Op/Add57.) Indeed, the Tax Court specifically criticized Berneman for failing to "make upward adjustments to the royalty rates" to "account for lump-sum payments" (Op/Add126), but then made the same error in its own royalty-rate computation (Op/Add133-138).

If the upfront payment and the cross-license had been properly accounted for, as § 1.482-1(d)(3)(ii)(A)(1) requires, then the actual starting royalty rate would have been much more than 7%. That upward adjustment to the Pacesetter agreement's value, in turn, would impact the other adjustments made by the Tax Court that were computed by reference to that value. On remand, if the CUT method is utilized, the Tax Court should reassess the original "value" of the Pacesetter agreement to account for all of the consideration received, and then recompute each adjustment that was based on the original Pacesetter value.

2. Uniform rate for Devices and Leads

The Tax Court further erred in determining that the royalty for Leads should be "half of the 44%" royalty for Devices. (Op/Add138.) There is no sound basis in the record for reducing the adjusted Pacesetter royalty rate by 22% for Leads. The Pacesetter agreement had one royalty that applied to both cardiac "devices" and cardiac "leads." (App689.) That Medtronic utilized different royalty rates in its Intercompany-Licenses — as the court observed when addressing the issue of the arm's-length rate for Leads (Op/Add138) — is irrelevant. A

court cannot set arm's-length prices by relying on prices in the controlled transactions in question. To do so defeats the entire purpose of Section 482 and the related regulations. *See Perkin-Elmer Corp. v. Commissioner*, 1993 WL 338983, at *64 (T.Ct. 1993) ("Ordinarily, in an arm's-length analysis under section 482, we disregard transactions between the taxpayer and a related entity.").

Nor does the Tax Court's assertion that the "device operations were substantially more profitable than the leads operations" (Op/Add138) justify a 22% reduction in the royalty rate for Leads. First, even if that assertion were accurate (which it is not), the court's 22% adjustment based on the purported profit-potential differential between Leads and Devices cannot be squared with the court's "3.5%" adjustment based on the profit-potential differential between Pacesetter and Medtronic (Op/Add136). The court provides no explanation for that arbitrary inconsistency. The court rationalized that a 3.5% upward adjustment was sufficient to account for the profit-potential difference between Pacesetter and Medtronic because (in the court's view) profit potential does not have a large "impact on the value of the licenses" (Op/Add136) but inexplicably took a different view when adjusting the

rate for Leads downward by 22% to account for the purported profit-potential difference between Leads and Devices.

Moreover, the Tax Court's assertion about the relative profitability of Devices and Leads is unsupported by the evidence. Although Medtronic earned more revenue from Devices than from Leads because the prices for Devices were higher than those for Leads (Op/Add7), revenue is not the same as profit. Profit must take into account costs. In fact, Leads were slightly more profitable than Devices because the operating profit margins on Leads were slightly higher than those on Devices during 2005-2006.[17] *See*, above, n.8.

Medtronic presented no evidence that an unrelated party in negotiating royalty rates for Medtronic Leads and Devices would insist on different rates. To the contrary, in the Pacesetter agreement, an unrelated party paid the exact same royalty for Medtronic cardiac leads and devices. The same should hold true for the Intercompany-Licenses.

[17] The Tax Court did not explain what it meant by "profitable" in comparing Devices and Leads (Op/Add138), but operating profit margins are the primary driver of royalty rates (App869).

3. Revised profit-potential adjustment

Finally, as explained above (§ B.6), the Tax Court failed to analyze the "profit potential" of the Pacesetter agreement and the Intercompany-Licenses, as § 1.482-4(c)(2)(iii)(B)(1)(ii) expressly requires. Rather than analyze the agreements' profit potential for purposes of determining whether the profit potential was sufficiently similar so that the Pacesetter agreement could qualify as a CUT, the Tax Court simply assumed that to be the case and made an arbitrary adjustment to the Pacesetter royalty to account for the higher profitability of the Intercompany-Licenses. (Op/Add135-136.) To account for that greater profit potential, the Tax Court made "an upward adjustment of 3.5%" (Op/Add136), without first calculating the actual difference in profitability, despite the evidence in the record addressing that issue (App585-587, 817-818). As noted above, Medtronic's operating margin was 52.6% whereas Pacesetter's was 17.7%, as the Commissioner emphasized but the Tax Court ignored. (App595.) That evidence should be considered on remand, if the Pacesetter agreement is treated as if it were a CUT.

CONCLUSION

The decision of the Tax Court should be reversed and the case remanded for the court to determine an arm's-length royalty rate for the Intercompany-Licenses utilizing the CPM, or, alternatively, to revise the adjustments made to the Pacesetter royalty rate.

Respectfully submitted,

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JULY 2017

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Attorney for Commissioner of Internal Revenue

Dated: July 21, 2017

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EXHIBIT 64

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